EXHIBIT 4

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LATHAM & WATKINS LLP

File No. 044496-0029

May 4, 2010

VIA ECF & FACSIMILE

The Honorable Douglas E. Arpert, U.S.M.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Bldg. & U.S. Courthouse
402 East State Street, Room 2020
Trenton, New Jersey 08608

Re: *Wyeth v. Orgenus Pharma Inc. and Orchid Chemicals & Pharmaceuticals Ltd.*, Civil Action No.: 09-3235 (FLW/DEA)

Dear Judge Arpert:

We represent Defendants Orgenus Pharma Inc. and Orchid Chemicals & Pharmaceuticals Ltd. (collectively "Orchid") in the above-referenced matter. We write to respond to Wyeth's April 30, 2010 letter concerning Orchid's request that the Court compel Wyeth to produce: (1) any license agreements entered into relating to the asserted patents (which concern generic versions of the very drug at issue in this case); and (2) any settlement agreements resolving those earlier cases.

Wyeth ignores that Orchid seeks the production of two separate categories of agreements – license agreements and settlement agreements – under two separate document requests. Wyeth fails to distinguish between the two categories and cites cases that relate only to settlement agreements. None of the cases Wyeth cites, however, provide any support for the notion that the license agreements sought here are not discoverable on the grounds set forth in Orchid's April 22, 2010 letter. Indeed, at page 3 of its letter, Wyeth admits that "all of Wyeth's prior settlement agreements" ***preceded*** any "license agreements" that it entered into with the defendants in the prior venlafaxine cases. The fact that the license agreements were entered into after the settlement agreements puts them clearly outside the scope of the case law cited by Wyeth.

Further, the prior licenses entered into by Wyeth regarding venlafaxine are clearly relevant to this case and are not rendered nondiscoverable merely because Wyeth entered into them with parties that it had previously sued. The Federal Circuit has made clear that such licenses are, indeed, discoverable in patent cases. *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d

860, 872 (Fed. Cir. 2010) (stating with respect to the determination of a reasonable royalty that "the most reliable license in th[e] record arose out of litigation"); *see also Datatreasury Corp. v. Wells Fargo & Co.*, Civil Action No. 2:06-CV-72 DF, 2010 WL 903259, at *2 (E.D. Tex. Mar. 4, 2010) ("In light of *ResQNet*, litigation-related licenses should not be excluded . . . .").

Wyeth's argument that Orchid's application is just a pretext for obtaining an "advantage" in settlement negotiations is flat out wrong. Preliminarily, we note that it is simply not true that Orchid has refused to discuss settlement without the sought documents. In fact, after the settlement communication which Wyeth quotes in its April 30 letter, Orchid did in fact communicate its settlement position to Wyeth, and Wyeth has not responded. Further, Orchid requested these documents in September 2009, long before Wyeth suggested a settlement meeting. Orchid requested those documents because they contain information that is relevant and reasonably calculated to lead to the discovery of admissible evidence for the reasons set out in our April 22 letter. The fact that prior litigants may or may not have agreed to pay royalties to Wyeth and if so what the royalty rates were is also relevant to how Orchid might respond to Wyeth's settlement demands does not render the information non-discoverable. Rather, it appears that Wyeth is resisting the discovery of relevant documents in order to preserve what it perceives as a negotiating advantage over Orchid. The pertinent inquiry is whether the information sought is discoverable under Rule 26, which provides for broad and liberal discovery. *See Kopacz v. Delaware River & Bay Auth.*, 225 F.R.D. 494, 497 (D.N.J. 2004) ("Courts have construed Rule 26 liberally, creating a broad range for discovery which would encompass any matter that bears on or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case") (citations and internal quotation marks omitted); *see also State of New York v. U.S. Metals Refining Co.*, 771 F.2d 796, 805 (3d Cir. 1985) ("Rule 26 provides very broad discovery.").[1] As demonstrated in Orchid's April 22nd letter, courts considering that question hold that, at a minimum, the documents sought here are relevant, discoverable and admissible in connection with issues concerning commercial success, other

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[1] Indeed, Wyeth's cases are either inapposite or support production of the documents Orchid seeks. *Centillon Data Sys., Inc. v. Ameritech Corp.*, 193 F.R.D. 550 (S.D. Ind. 1999) (no indication that the defendant made any showing of relevance, much less that issues of obviousness, damages, injunctive relief or patent misuse were raised); *Wyeth v. Lupin*, Civil No. 1:07-cv-00632-WDQ (D. Md. Mar. 28, 2008) (defendant sought broad settlement information without providing any specific grounds or alternative basis for obtaining the discovery); *Ford Motor Co. v. Edgewood Properties, Inc.*, 257 F.R.D. 418 (D.N.J. 2009) (defendant sought settlement negotiations in environmental litigation); *Dent v. Westinghouse*, MDL No. 875, 2010 WL 56054, at *2 (E.D. Pa. Jan. 4, 2010) (asbestos litigation); *Griffin v. Mashariki*, No. 96 Civ. 6400, 1997 WL 756914, at *2 (S.D.N.Y. Dec. 8, 1997) ("**Settlement-related information, including settlement agreements . . . are discoverable without a heightened showing of relevance."**; allowing discovery of settlement materials); *Doe v. Methacon Sch. Dist.*, 164 F.R.D. 175 (E.D. Pa. 1995) (non-patent; defendant made only the conclusory statement that the settlement information sought was "clearly relevant" and could lead to the admissible evidence); *Shipes v. BIC Corp.*, 154 F.R.D. 301, 309 (M.D. Ga. 1994) (products liability; the requirement of a particularized showing "allow[s] discovery of [settlement information] if the information is truly relevant."); *Bottaro v. Hatton Assocs.*, 96 F.R.D. 158 (E.D.N.Y. 1982) (non-patent case where the terms of a settlement were sought in connection with damages).

secondary considerations of non-obviousness, damages, the appropriateness of injunctive relief, and patent misuse.

Indeed, it was Wyeth that put secondary considerations of non-obviousness, and specifically, commercial success, at issue in this case. Wyeth acknowledged in the parties' Joint Discovery Plan that "Wyeth anticipates that fact discovery will be needed concerning . . . the commercial success of Effexor XR®."[2] Joint Discovery Plan, at 5 (attached as Ex. Q). Likewise, in its Rule 26(a)(1) disclosures, Wyeth disclosed two witnesses "that Wyeth may use to support its claims or defenses" concerning the "commercial success of Effexor XR®." Wyeth's Initial Disclosure Statement Pursuant to Fed. R. Civ. P. 26(a)(1), at 4, ¶¶ 5-6 (attached as Ex. R). Wyeth's Initial Disclosures further revealed that "[d]ocuments regarding the commercial success of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities." *Id.* at 6, ¶ 7.

Having put secondary indicia at issue, Wyeth cannot now seek to selectively exclude evidence on the criteria pertinent to that overarching issue. Interpreting its previous holding in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court of the United States wrote that courts considering the issue of obviousness are "to look at any secondary considerations that would prove instructive." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 127 S. Ct. 1727; 167 L. Ed. 2d 705 (2007). Wyeth attempts to turn *KSR* on its head by effectively seeking the exclusion of evidence concerning its licensing practices at the discovery stage and in the face of its own representation that it is, indeed, relying on commercial success to demonstrate non-obviousness. The documents sought here are undeniably pertinent to that issue. *See Datapoint Corp. v. Picturetel Corp.*, No. 3:93-cv-2381, 1998 WL 51356 (N.D. Tex. Jan. 23, 1998) ("agreements obtained in settlement of a litigation [are often used] to show the commercial success and nonobviousness of a patent"); *Am. Standard, Inc. v. Pfizer, Inc.*, MISC 87-1-73-IP, 1988 WL 156152, at *2 (S.D. Ind. July 8, 1988) ("[A]greements to license allegedly infringing products can be probative evidence of [commercial success and non-obviousness which are] relevant to the validity of a patent.").

Further, as reflected in *Griffin v. Mashariki*, (cited on page 2 of Wyeth's April 30 letter), Rule 408 does not limit disclosure of settlement materials during discovery. And *Griffin* notes that the prior venlafaxine settlement agreements could be admissible to impeach Wyeth's testimony regarding commercial success:

> Rule 408 of the Federal Rules of Evidence precludes the use of settlement-related materials as a means of establishing or disproving liability, but expressly allows for the use of such materials at trial for certain purposes, including impeachment. Notably, Rule 408 does not limit disclosure of settlement materials during discovery.

1997 WL 756914, at *2 (attached as Ex. S).

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[2] Effexor XR® is the brand name Wyeth uses to market venlafaxine.

Therefore, we respectfully request that this Court order the production of the requested license agreements and settlement agreements.

Respectfully submitted,

s/ Jason B. Lattimore

Jason B. Lattimore
of LATHAM & WATKINS LLP

Enclosures

cc: All Counsel of Record via ECF

EXHIBIT Q

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. and ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-03235 (FLW)(DEA) **JOINT DISCOVERY PLAN** Rule 16 Conference November 12, 2009 DOCUMENT FILED ELECTRONICALLY

I. THE PARTIES AND THEIR ATTORNEYS

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II. BRIEF DESCRIPTION OF THE CASE, INCLUDING FACTS, CAUSES OF ACTION AND AFFIRMATIVE DEFENSES ASSERTED

This is a civil action for patent infringement under the patent laws of the United States and, in particular, under 35 U.S.C. § 271(e). This action arises from an abbreviated new drug application ("ANDA") filed by Orchid with the United States Food and Drug Administration ("FDA") seeking approval for Orchid to market a generic version of venlafaxine hydrochloride

extended-release capsules before the expiration of Wyeth's patents-in-suit. Venlafaxine hydrochloride extended-release capsules are currently marketed by Wyeth under the brand name Effexor XR®.

In response to Orchid's May 19, 2009 Notice letter providing Orchid's non-infringement and invalidity allegations and after review of Orchid's ANDA provided by Orchid on June 4, 2009, Wyeth filed its Complaint in this action on July 2, 2009. Wyeth seeks, among other things, (1) a judicial declaration that the commercial manufacture, use, offer for sale, sale or importation of Orchid's venlafaxine hydrochloride extended-release capsules would infringe Wyeth's patents-in-suit; (2) an order in accordance with 35 U.S.C. § 271(e)(4)(A) prohibiting FDA approval of Orchid's ANDA until the expiration of the patents-in-suit; and (3) injunctive relief against Orchid under 35 U.S.C. § 271(e)(4)(B).

On September 2, 2009, Orchid filed its Answer to the Complaint, denying infringement and asserting defenses of non-infringement, invalidity, and unenforceability of the patents-in-suit. Orchid denied that Wyeth is entitled to any of the relief requested in its Complaint. Orchid further filed Counterclaims seeking a declaration that its ANDA product does not infringe and would not infringe (either directly or indirectly) any claims of the patents-in-suit and that the claims of the patents-in-suit are invalid and unenforceable.

Wyeth filed its Answer to Defendants' Affirmative Defenses and Counterclaims on September 25, 2009.

III. STATUS OF SETTLEMENT DISCUSSIONS

The parties have communicated regarding settlement, but they have not reached agreement. The parties expect to continue settlement discussions.

IV. THE PARTIES' FED. R. CIV. P. 26(A)(1) DISCLOSURES

The parties exchanged the information required by Fed. R. Civ. P. 26(a)(1) on October 1, 2009.

V. DISCOVERY CONDUCTED TO DATE AND PROBLEMS ENCOUNTERED

A. Discovery Conducted To Date

Orchid produced its entire ANDA 91-123 to counsel for Wyeth on June 4, 2009. Wyeth served interrogatories, requests for production of documents, and requests for admission on Orchid on September 22, 2009. Orchid served written responses on October 26, 2009. Orchid served requests for production of documents on Wyeth on September 21, 2009. Wyeth served written responses on October 26, 2009.

B. Discovery Problems Encountered To Date

Orchid sent Wyeth a letter on October 30, 2009 objecting to its responses to Orchid's Requests For Production and requesting a meet-and-confer to resolve the issues. Wyeth responded to that letter on November 4, 2009. Also on November 4, 2009, Wyeth sent Orchid a letter objecting to Orchid's discovery responses, and requesting a meet-and-confer to resolve those issues. The parties plan to meet and confer on November 5, 2009. No additional discovery problems have been encountered to date.

VI. ANTICIPATED FURTHER DISCOVERY NEEDS

Wyeth's position: The present suit against Orchid is the thirteenth such action Wyeth has brought against companies seeking FDA approval to market generic versions of Wyeth's extended-release venlafaxine hydrochloride product pursuant to an ANDA submitted to the FDA. As in those cases, Wyeth bears the burden of proving patent infringement and is faced with multiple counterclaims challenging its three patents. In previous cases, Wyeth has sought extensive discovery on the defendants' proposed products and their use, including, for example,

information relating to the generic product formulation and development process, the decision to pursue a generic version of Effexor XR®, research and development, the planned promotion and sales of those generic products, and the preparation of the ANDAs for those products.

In those cases where discovery has been taken, Wyeth completed substantially all such fact discovery against the defendant prior to submitting its opening claim construction brief. Wyeth intends to pursue the same extensive discovery from Orchid in this case.

In particular, Wyeth anticipates that fact discovery will be needed concerning infringement of the patents-in-suit, Orchid's ANDA No. 91-123 and the products that are the subject of that ANDA, including all design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA No. 91-123 and the products that are the subject of the ANDA; any information Orchid has regarding Effexor XR® and the patents-in-suit, including but not limited to use by Orchid of the patents-in-suit and/or Effexor XR® in developing the products that are the subject of ANDA No. 91-123, the commercial success of Effexor XR® and the side-effects associated with immediate-release venlafaxine, and Orchid's basis for submitting its ANDA to the FDA with a Paragraph IV certification and for bringing affirmative defenses and counterclaims asserting that the patents-in-suit are invalid, unenforceable, or not infringed by Orchid's extended-release venlafaxine products. This discovery is relevant to rebutting Orchid's invalidity allegations. Regarding claim construction, in particular, Wyeth anticipates that fact discovery will be needed concerning the understanding of Orchid personnel of various disputed claim terms, such as "extended release formulation" and "diminished incidences of nausea and emesis." Wyeth further anticipates the need for fact discovery regarding the use by Orchid of Wyeth's patents in developing Orchid's generic version of Effexor XR®. Such fact discovery is relevant to the claim construction issues

in this case, *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Wyeth also anticipates the need to take the depositions of any experts Orchid may rely upon to support its claim construction positions. Indeed, the local patent rules expressly recognize the need for such discovery and the exchange of other information prior to *Markman* briefing. *See* Patent rule 4.4. The fact that Wyeth has asserted the patents-in-suit in prior cases against other generic drug manufacturers with different drug formulations and different claim construction theories does not justify dispensing with the procedures for claim construction established under this Court's patent rules.

Wyeth, moreover, anticipates that it will produce over one million pages of documents, including the pleadings, expert reports, and Wyeth's discovery responses from the related cases. While the availability of this extensive prior discovery should reduce Orchid's need for discovery from Wyeth in this case, defendants in the related cases that likewise received prior discovery and pleadings nonetheless have aggressively pursued additional discovery, including seeking to re-depose fact witnesses who have given multiple depositions in the prior related cases. Defendants in the prior cases have also insisted on conducting their own depositions of Wyeth under Rule 30(b)(6), despite access to Wyeth's comprehensive Rule 30(b)(6) testimony from prior related cases and despite initially insisting in several cases that extensive discovery from Wyeth would be unnecessary.[1]

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[1] In the *Wyeth v. Teva* litigation, the parties took a total of 37 depositions consisting of 11 expert depositions, 5 Rule 30(b)(6) depositions, and 21 fact depositions. The depositions spanned a period of 13 months. In the *Wyeth v. Impax* litigation, the parties took a total of 29 depositions consisting of 10 expert depositions, 9 Rule 30(b)(6) depositions, and 10 fact depositions. The depositions spanned a period of over 10.5 months. In the *Wyeth v. Anchen* litigation, the parties took a total of 24 depositions consisting of 13 expert depositions, 1 Rule 30(b)(6) deposition, and 10 fact depositions. The depositions spanned a period of 13 months. In the *Wyeth v. Lupin* litigation, the parties took a total of 30 depositions consisting of 14 expert depositions, 2 Rule 30(b)(6) deposition, and 14 fact depositions. The depositions spanned a period of 7 months. In the *Wyeth v. Mylan* litigation, the parties took a total of 19 depositions consisting of 9 expert depositions, 2 Rule 30(b)(6) deposition, and 8 fact depositions. The depositions spanned a period of 8 months. In the *Wyeth v. Sandoz*, litigation, the parties took a total of 9 depositions consisting of 4 expert

(continued on next page)

Furthermore, expert disclosures are a necessary element in a technologically complex case such as this. Wyeth contemplates providing expert testimony on at least the areas of psychiatry, pharmacokinetics, pharmacodynamics, pharmaceutical formulations, biostatistics, and economics. Wyeth further anticipates that Orchid will designate opposing experts and that extensive expert depositions will be conducted.

Accordingly, as set forth in Section VII below, Wyeth proposes approximately 8 months from now for fact discovery and approximately 7 weeks for expert discovery in this case, which is comparable to the discovery periods in the prior related cases, as the following chart shows:

(continued from previous page)
depositions, 2 Rule 30(b)(6) depositions, and 3 fact depositions. The depositions spanned a period of 12 months. In the *Wyeth v. Apotex* litigation, the parties took a total of 33 depositions consisting of 14 expert depositions, 3 Rule 30(b)(6) depositions, and 16 fact depositions. The depositions spanned a period of 5 months.

Table A

DEFENDANT	CASE NO. (COURT)	COMPLAINT FILED	FACT DISCOVERY DEADLINE	MARKMAN HEARING — ORDER ISSUED	TRIAL DATE
Teva	CV 03-1293 (NJ)	3/24/2003	9/2/2004	8/29/2005 — 9/6/2005	10/11/2005 (Settled on eve of trial)
Impax	CV 06-222 (DE)	4/5/2006	None	6/12/2007 — 12/13/2007	4/9/2008 (Settled on eve of trial)
Anchen	CV 06-386 JVS (CD Cal)	4/12/2006	11/16/2007	11/9/2007 — 12/21/07	9/9/2008 (Settled)
Lupin	07-CV - 00632 (MD)	3/12/2007	5/20/2008	Not Conducted	3/23/2009 (Settled)
Osmotica	7:07-CV-67-D (EDNC)	4/20/2007	3/31/2008	1/22/2008	N/A (Settled on eve of *Markman* Hearing)
Sandoz	07-CV-00234 (EDNC)	6/22/2007	10/29/2008	5/29/2008 — 7/3/2008	TBD
Mylan	07-CV-91 (NDWV)	7/6/2007	3/31/2009	3/2/2009 — 5/22/2009	10/13/2009 (Settled on eve of trial)
Wockhardt	CV 07-5166 JVS (CD Cal)	8/8/2007	N/A	N/A	(Settled)
Biovail	TBD (DE)	6/26/2008	N/A	N/A	TBD

DEFENDANT	CASE NO. (COURT)	COMPLAINT FILED	FACT DISCOVERY DEADLINE	MARKMAN HEARING — ORDER ISSUED	TRIAL DATE
Apotex	08-22308-CIV-MORENO	8/18/2008	3/6/09	Claim Construction rendered in Magistrate Judge Torres' Summary Judgment Report Rendered on August 15, 2009, Pending Review by U.S. District Judge Moreno	1/19/2010
Torrent	09-019 (JJF)	1/8/2009	TBD	TBD	TBD (Stayed)
Zydus	09-239 (JJF)	4/9/2009	TBD	TBD	TBD

Orchid's position: Rather than adopting an artificially prolonged schedule at the outset, the better approach under the circumstances is to provide the parties with an expedited schedule for the completion of discovery. Orchid believes that, because Wyeth has already litigated in twelve prior cases the same issues that are at issue here, this case can and should be expedited and placed on a faster track than if this were the first case that Wyeth had instituted concerning generic extended-release venlafaxine. In light of the existence of the records from the twelve similar cases that Wyeth has brought, Orchid believes that it will need to conduct only targeted supplemental discovery. Orchid promptly served document requests on Wyeth seeking production of, among other things, all filings, court transcripts, and expert reports from those twelve earlier cases. Wyeth has not yet produced any documents in response to that request. Hence, at this time, Orchid cannot yet make informed judgments about what additional discovery

it will need to conduct. However, based on the extensive records developed in the twelve prior cases, Orchid fully expects that it will need to take only limited additional discovery in this case.

Orchid believes that Wyeth overestimates the amount of discovery required both before Markman briefing and for the case as a whole. Orchid expects that Wyeth will proffer the same claim construction positions in this case as it did in the previous twelve cases. Orchid does not believe that Wyeth needs any additional fact discovery from Orchid concerning claim construction of Wyeth's own patents for Markman briefing. The "design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA" that were conducted in 2008 cannot have any bearing on the construction of claims in a patent filed over a decade earlier, in 1996. With respect to its burden of proving infringement, Wyeth has to establish (as in the previous cases) that "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). "Of course, this hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support." Id. Again, the "design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA" have little, if any, bearing on the issue of infringement. In any event, Orchid expects to promptly provide Wyeth with the "extensive discovery from Orchid" described above.

VII. THE PARTIES' MEETING PURSUANT TO FED. R. CIV. P. 26(f)

The parties first met and conferred pursuant to Fed. R. Civ. P. 26(f) by telephone on September 17, 2009, and have continued their discussion since that time.

The parties have worked together to try to reach agreement on the dates and other topics that are the subject of this plan.

To the extent the parties were unable to agree on a particular issue, the parties' competing proposals are presented.

	Local Patent Rule (where applicable)	Wyeth's Proposed Schedule	Orchid's Proposed Schedule
Initial Scheduling Conference		11/12/2009	11/12/2009
Defendant invalidity and noninfringement contentions due	3.6(b), (d) (14 days)	11/26/2009 (14 days)	11/19/2009 (7 days)
Plaintiffs asserted claims and infringement contentions due	3.6(f) (45 days)	1/8/2010 (45 days)	12/3/2009 (14 days)
Exchange claim terms	4.1 (14 days)	1/22/2010 (14 days)	12/10/2009 (7 days)
Exchange proposed constructions	4.2 (21 days)	2/12/2010 (21 days)	12/17/2009 (7 days)
Deadline for joining other parties and amending the pleadings		2/26/2010	2/26/2010
Joint claim construction statement	4.3 (30 days)	3/12/2010 (28 days)	1/8/2010 (22 days)
Complete claim construction discovery	4.4 (30 days)	4/9/2010 (28 days)	2/15/2010 (38 days)
Opening *Markman* Briefs	4.5 (45 days)	4/23/2010 (42 days)	3/5/2010 (18 days)
Responding *Markman* Briefs	4.5 (60 days)	6/22/2010 (60 days)	4/2/2010 (28 days)
Confer re claim construction hearing schedule	4.6 (2 weeks)	7/6/2010[2] (2 weeks)	4/9/2010 [3] (7 days)

[2]Wyeth submits that live testimony is not required for the claim construction hearing, and that four hours should be sufficient for the hearing. Wyeth does not believe that a separate tutorial is necessary.

[3] Orchid proposes that the court decide the length of the hearing, whether to have live testimony and whether a separate tutorial is needed.

	Local Patent Rule (where applicable)	Wyeth's Proposed Schedule	Orchid's Proposed Schedule
Close of Fact Discovery		7/30/2010	5/21/2010
Opening Expert Reports		11/22/2010[4]	6/18/2010
Responsive Expert Reports		1/15/2011	7/16/2010
Close of Expert Discovery		2/28/2011	9/03/2010
Filing opening briefs in support of dispositive motions		3/31/2011	9/17/2010
Proposed Trial Date		7/18/2011	1/10/2011

Wyeth's Comments Regarding Orchid's Proposal

Wyeth has already explained the bases and rationale for its proposed schedule, which Wyeth submits is entirely consistent with the timeframes set forth in the local patent rules. (See Section VI, above). Wyeth submits Orchid's proposal, which significantly truncates many of the patent rules' deadlines, is unworkable because, among other things, it does not provide enough time for discovery before *Markman* briefing, does not provide enough time for discovery in general, and key dates in the schedule conflict with the schedule in *Wyeth v. Apotex*, where trial begins on January 19, 2010, and will be preceded by extensive pretrial preparation involving the same attorneys, fact witnesses, and experts who will be involved in discovery and *Markman* proceedings in this case.

Furthermore, Orchid's proposed schedule is inconsistent with the schedules in the prior related cases, as shown above. In particular, Orchid's schedule is at odds with the schedules

[4] Wyeth proposes this date to allow sufficient time for a Markman hearing and for the Court to issue a claim construction order. Wyeth submits that requiring expert reports before the Court's Markman order would be inefficient and would impose unnecessary burdens and expense on the parties.

adopted by the two other courts that, like New Jersey, have adopted patent rules. In *Wyeth v. Anchen*, (C.D. Cal.) the court set the discovery to close 19 months from the date of the complaint, while in *Wyeth v. Sandoz*, (E.D.N.C.) discovery ended 16 months from the date of the complaint. Orchid's proposed schedule, in contrast, would compress all discovery into just 14 months from the date of the complaint.

It is particularly unrealistic to propose, as Orchid does, that all claim construction discovery be completed by February 15, 2010, just three months from now. The parties have not yet produced documents in response to each other's document requests. What is more, experience has shown the futility of compressed schedules such as Orchid proposes. In *Wyeth v. Apotex*, for example, the court initially issued accelerated schedule and declined to modify it after Apotex insisted that it needed only minimal discovery. Ultimately, that expedited schedule could not be met, and the Court granted Wyeth's renewed motion to push back all dates. Instead of a trial in February 2009, trial was rescheduled for June 2009. Even then, the modified schedule proved inadequate, leaving the court insufficient time to address dispositive motions and in limine motions. The court *sua sponte* pushed back the trial date by another four months. Similar problems occurred in *Wyeth v. Lupin,* where the Court initially adopted an accelerated schedule after Lupin represented that it required only minimal deposition discovery from Wyeth. Lupin then sought to depose numerous Wyeth fact witnesses, necessitating an extension of the discovery period and other dates. Orchid's suggestion that Wyeth should prepare its *Markman* briefs by "rote" ignores the fact that this case, like each of the preceding cases, is unique. Orchid has yet to set forth claim construction positions, and therefore, it is entirely premature to conclude that "shortcuts" to conducting claim construction proceedings and fact discovery should be implemented here. Orchid suggests that accelerating *Markman* proceedings may

facilitate settlement. (*See* p. 16). But there is no assurance that a *Markman* ruling will result in a prompt settlement. In Wyeth *v. Sandoz*, for example, the court issued its *Markman* ruling on July 3, 2008. That case remains pending.

In short, Orchid's proposed schedule departs significantly from the orderly progression of events contemplated by the local patent rules. It also departs significantly from the schedules adopted by the other courts in related prior Effexor XR litigations. Those schedules, like the one proposed here, are consistent with the timetable for litigations envisioned by Congress under the Hatch-Waxman Act. The Act provides for a 30-month stay of approval for Orchid's ANDA while this case is being litigated. Wyeth's proposed trial date of July 18, 2011 is three months prior to the expiration of the 30-month stay in this case, and thus provides for resolution of this case in an appropriate timeframe as contemplated by the Hatch-Waxman Act. Orchid suggests that an expedited trial in this case would provide an opportunity to launch its generic product after Teva's exclusivity expires at the end of 2010. (*See* p. 16). Orchid, however, does not factor in an appeal to the Federal Circuit by Wyeth in the event of a judgment in Orchid's favor. If Orchid were to launch its product before appellate review by the Federal Circuit, that launch would be "at risk" and would expose Orchid to the prospect of substantial monetary damage if the Federal Circuit were to reverse a district court judgment in Orchid's favor. Because of that huge financial exposure, generic drug manufacturers rarely undertake such "at risk" launches. Furthermore, even with a trial in January, 2010, as Orchid proposes, the Federal Circuit would likely not decide an appeal from the district court's judgment until after June, 2011. Finally, Orchid does not state that the FDA has finished reviewing its ANDA and has tentatively approved Orchid's generic product. Without such tentative approval, Orchid cannot launch its product regardless of the outcome of this case.

Orchid's Comments Regarding The Proposed Schedules

As noted above in Orchid's comments, Orchid submits that this is not a typical patent case requiring a typical patent discovery schedule. Claim construction has been briefed at least seven times previously, including once in this Court before Judge Martini. There is no legitimate reason why Wyeth cannot meet Orchid's proposed Markman schedule. Wyeth has had Orchid's non-infringement and invalidity contentions and a copy of its entire ANDA 91-123 for over five months. That is more than ample time for Wyeth to formulate and provide its infringement contentions. Even assuming the relevance of Wyeth's counsel's schedules in other cases that Wyeth has chosen to bring, the only activity required of Wyeth's counsel in this case prior to its scheduled trial date with Apotex involves the recitation of its previous claim construction positions. The proposed schedule also provides a reasonable time after the Apotex trial will be completed before opening Markman briefs are due. Further, according to Wyeth's Table A, there is a substantial possibility that the Apotex case will settle—given that most of the cases settled shortly after the Markman order issued. In any event, Wyeth's opening Markman brief would again merely require only rote recitation of its previous Markman positions.

Wyeth points out that discovery in Wyeth v. Sandoz was completed 16 months after the complaint was filed. Orchid proposes that discovery in this case be completed 14 months after the complaint was filed. As Wyeth notes above, "the availability of this extensive prior discovery should reduce Orchid's need for discovery from Wyeth in this case." Indeed, Orchid reasonably believes that much of the discovery accomplished in the prior cases will not have to be repeated in this case.

This patent case is governed by the Hatch-Waxman statutes. Under this statutory scheme, Orchid's ANDA 91-123 is subject to a 30-month stay of approval whereby FDA is

prevented from granting marketing approval for Orchid's ANDA until the earlier of November 21, 2011 or the date a district court decides the asserted patents are invalid or not infringed by Orchid's ANDA product. Pursuant to the settlement with Teva, Wyeth has permitted Teva to launch its generic product on July 1, 2010. Under the Hatch-Waxman statutory scheme, Teva (along with Wyeth) will have marketing exclusivity until December 28, 2010, after which time FDA will be permitted to approve all other ANDAs not otherwise subjected to a 30-month stay. Orchid's proposed schedule would permit Orchid the potential opportunity to launch its ANDA product shortly after the FDA would be permitted to approve all ANDAs if this Court renders a decision in its favor. In contrast, Wyeth's proposed schedule pushes the potential approval date of Orchid's ANDA almost to the expiration of the 30-month stay, after which Orchid's ANDA could be approved absent a finding of invalidity or non-infringement. Wyeth's proposed schedule conflicts with the Hatch-Waxman statutory scheme, which requires that each of the parties shall "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

Orchid's proposed schedule encourages a quick Markman order. In the prior venlafaxine cases the Markman order was soon followed by settlement. Under any of the previous Markman orders, Orchid is confident it will prevail on either non-infringement or invalidity at trial.

There is much upside to adopting Orchid's proposed schedule. If Orchid is correct that the documents that is has already requested from Wyeth contain the vast majority of the discovery that would ordinarily be taken in a "first" case on a patent, then the schedule it proposes will be more than adequate for the parties, and this case can be expeditiously resolved. Orchid's schedule is wholly consistent with the objectives of the Hatch-Waxman statutory scheme, and has the greatest likelihood of resolving this case promptly. Conversely, there is no downside to adopting Orchid's proposed schedule. If it turns out that, for whatever reason, the

schedule will need to be adjusted in the future, then that can easily happen either by agreement of the parties or by ruling of the Court. Adopting Wyeth's proposed schedule at the outset on the assumption that this case will proceed as slowly as a "first" case serves no purpose, would slow the disposition of this case, and is contrary to the public policy underpinnings of the Hatch Waxman Act.

VIII. OTHER DISCOVERY MATTERS

A. Interrogatories

The parties do not seek any change to the limitations imposed under the Federal or Local rules.

B. Depositions

The parties agree that each side shall be permitted to take 10 fact depositions and further agree that the limitation of 10 depositions per side is inapplicable to expert depositions.

Orchid requests that the Court permit the deposition(s) of Orchid fact witness(es) who are located in India to take place by video conference.

Wyeth requests that the Court require that Orchid fact witnesses who are located in India be required to present themselves for deposition within this judicial district or at a place agreed to by the parties. To date, Orchid has identified just one individual in its Rule 26(a) declaration and in responses to interrogatories as having knowledge of the subject matters at issue in this case. Requiring Wyeth to depose that individual, and others in India who undoubtedly possess discoverable information by video conference, will unnecessarily hamper discovery and will disadvantage Wyeth. Deposition by video conference simply is not a viable alternative to a traditional deposition. Since Orchid has asserted multiple counterclaims in this case, it should be required to present witnesses residing in India for deposition in this judicial district.

C. Special discovery mechanisms or procedures

1. Electronic Discovery

Documents will be produced in single-page TIFF images except for minor exceptions, such as for clinical data.

2. Other Discovery Needs

The parties do not now anticipate any special discovery needs.

3. Protective Order

This action will require the disclosure of confidential or proprietary technical and financial information. The parties have submitted a stipulated discovery confidentiality order. The order includes provisions relating to materials protected under the attorney-client privilege or work product immunity, including procedures for dealing with the inadvertent production of such materials.

IX. EXPERT TESTIMONY

As reflected by the proposed schedule, the parties anticipate retaining expert witnesses. The proposed schedule set forth in Section VII offers the parties' respective proposed deadlines for the production of expert reports and for expert depositions.

X. ALTERNATIVE DISPUTE RESOLUTION

Wyeth submits that this case is not one that might be resolved by alternative dispute resolution. Such proceedings in prior related cases have not been fruitful.

Orchid submits that this case may potentially benefit from a settlement conference with the Magistrate Judge in early 2010.

Respectfully submitted,

CONNELL FOLEY LLP
Attorneys for Plaintiff

s/ Liza M. Walsh

LATHAM & WATKINS LLP
Attorneys for Defendants

s/ Jason B. Lattimore

Dated: November 5, 2009

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Attorneys for Plaintiff Wyeth

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. and ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-03235 (FLW)(DEA) **WYETH'S INITIAL DISCLOSURE STATEMENT PURSUANT TO FED. R. CIV. P. 26(a)(1)**

Plaintiff Wyeth provides this Initial Disclosure Statement in accordance with Fed. R. Civ. P. 26(a)(1). These disclosures are based on information reasonably available to Wyeth as of this date. Wyeth reserves the right to supplement or modify these disclosures.

Thus, Wyeth's disclosures represent a good faith effort to identify discoverable information it currently reasonably believes it may use to support its claims or defenses as required by Fed. R. Civ. P. 26(a)(1). These disclosures do not include information that may be used solely for impeachment purposes.

Wyeth's disclosures are made without waiving, in any way: (1) any claim of privilege or work product; (2) the right to object on the grounds of competency, relevancy and materiality, hearsay, or any other proper ground, to the use of any such information, for any purpose, in

whole or in part, in any subsequent proceeding in this action or any other action; and (3) the right to object on any and all grounds, at any time, to any other discovery request or proceeding involving or relating to the subject matter of these disclosures.

Finally, these disclosures do not identify or otherwise include information concerning experts, as that subject is not covered by Fed. R. Civ. P. 26(a)(1). Wyeth will provide its expert disclosures pursuant to the deadlines set forth in the Federal Rules of Civil Procedure or a Scheduling Order that will be entered by the Court.

All of the disclosures set forth below are made subject to the above objections and qualifications.

I. Rule 26(a)(1)(A) Disclosure

Based on information reasonably available to Wyeth at this time, the following are the names, and if known, the addresses of individuals who are likely to have discoverable information that Wyeth may use to support its claims or defenses, unless used solely for impeachment. The individuals identified may be contacted only through counsel for Wyeth. A brief identification of the subjects on which each listed individual may have such discoverable information is also provided. This list does not include Orgenus Pharma Inc.'s and Orchid Chemicals & Pharmaceuticals Ltd.'s ("Orchid's") employees, agents, or attorneys who are likely to have discoverable information that Wyeth may use to support its claims or defenses as Orchid is fully knowledgeable concerning the identity of and the subject matter known to those individuals.

1. Deborah M. Sherman

   Wyeth
   641 Ridge Road
   Chazy, New York 12921

Subject matter: inventor of United States Patent Nos. 6,274,171 B1; 6,403,120 B1; and 6,419,958 B2 ("the '171, '120, and '958 patents" respectively); subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

2. John C. Clark

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120 and '958 patents; research and development of extended release venlafaxine.

3. John U. Lamer

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

4. Stephen A. White

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

5. Dr. Eliseo Salinas
Adolor Corp.
700 Pennsylvania Drive
Exton, PA 19341

Subject matter: pharmacokinetic and clinical trials and publications relating to Effexor® and/or Effexor XR®; clinical advantages of Effexor XR®; commercial success of Effexor XR®.

6. Jay Bowsher

Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: the significance and importance of the development of Effexor XR®; commercial success of Effexor XR® as compared to Effexor®; drug development and importance of pharmaceutical research and development at Wyeth; ownership of the '171, '120, and '958 patents.

7. Robin P. Enever
18 Pine St
Rouses Point, New York 12979

Subject matter: research and development of extended release venlafaxine.

8. Xin Li
Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: knowledge of Wyeth's electronic database for Wyeth clinical studies involving immediate release venlafaxine and Effexor XR®, and the use of SAS programming to extract treatment emergent study event data from that database.

9. Peter Hunter
Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: IMS Health's data collection and storage, IMS Health products and services, and IMS Health's data on Effexor®, Effexor XR®, and other antidepressant products.

Wyeth expressly reserves the right to identify and call as witnesses additional persons if Wyeth learns during the course of its investigation and discovery in this action that such persons have knowledge of discoverable information that Wyeth may use to support its claims or defenses.

II. Rule 26(a)(1)(B) Disclosure

Based on information reasonably available to Wyeth at this time, Wyeth describes below by category and location the following documents, data compilations, and tangible things in the possession, custody, or control of Wyeth, that Wyeth may use to support its claims or defenses (excluding documents that may be used solely for impeachment):

1. Documents relating to the research, development, and commercialization of extended release venlafaxine HCl capsules as disclosed and claimed in the '171, '120, and '958 patents may be located at Wyeth's facilities in New York, Pennsylvania, and/or New Jersey, and/or at Finnegan Henderson facilities.

2. Documents relating to the preparation, filing, and prosecution of the '171, '120, and '958 patents may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

3. Documents relating to marketing and product sales of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

4. Documents demonstrating the advantages of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

5. Documents relating to the assignment and ownership of the '171, '120, and '958 patents may be located at Wyeth's facilities in Pennsylvania, New Jersey, and/or New York, and/or at Finnegan Henderson facilities.

6. Documents relating to the importance of pharmaceutical research and development at Wyeth may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

7. Documents regarding the commercial success of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

8. Documents relating to Orchid's ANDA filings for Venlafaxine HCl Extended-Release capsules are located at Orchid's facilities.

9. Documents relating to Orchid's infringement, the basis for Orchid's paragraph IV certification, its decision to pursue an extended-release venlafaxine product, and other documents relating to the exceptional nature of this case are located at Orchid's facilities.

III. Rule 26(a)(1)(C) Disclosure

Pursuant to Fed. R. Civ. P. 26(a)(1)(C), Wyeth states that under 35 U.S.C. § 271(e)(4)(C), damages or other monetary relief may be awarded in this action only if Orchid violates applicable laws and regulations and engages in the commercial manufacture, use, offering to sell or sale within the United States or importation into the United States of Venlafaxine HCl

Extended-Release capsules. To Wyeth's present knowledge, Orchid has not engaged in such commercial activity to date, and Wyeth therefore makes no claims for damages or other monetary relief in this action at this time. Wyeth reserves the right to assert such claims in the event that Defendants have engaged or do engage in such commercial activity before the expiration date of Wyeth's '171, '120, and '958 patents.

Wyeth seeks an award of its attorney's fees, pursuant to 35 U.S.C. § 285, and costs of suit. The amount of those fees and costs is not yet known.

IV. Rule 26(a)(1)(D) Disclosure

Wyeth is unaware of any apparently pertinent insurance agreements at this time. However, Wyeth reserves the right to supplement this disclosure if any pertinent insurance agreements are identified.

Dated: October 1, 2009

Respectfully submitted

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of **WYETH'S INITIAL DISCLOSURE STATEMENT PURSUANT TO FED. R. CIV. P. 26(a)(1)** was served by electronic mail upon the following counsel for Defendants:

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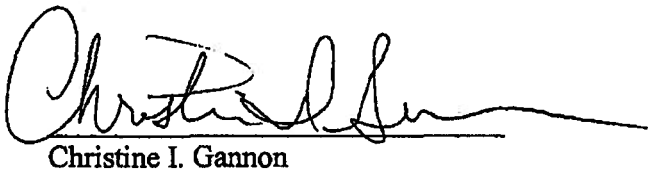

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EXHIBIT S

Not Reported in F.Supp., 1997 WL 756914 (S.D.N.Y.)
(Cite as: 1997 WL 756914 (S.D.N.Y.))

United States District Court, S.D. New York.
William GRIFFIN, Plaintiff,
v.
Zola MASHARIKI, Natosha Reid, and Janine Gilbert, Defendant.
No. 96 CIV. 6400(DC).

Dec. 8, 1997.

Glenn Greenwald, Esq., New York, New York, for Plaintiff.

Proskauer Rose LLP, Attorneys for Defendant Zola Mashariki, By Debra L. Kessler, Esq., New York, New York.

Paul, Weiss, Rifkind, Wharton & Garrison, Attorneys for Defendant Natosha Reid Robinson, By Leslie C. Murray, Esq., New York, New York.

Fried, Frank, Harris, Shriver & Jacobson, Attorneys for Janine Gilbert, By Rana Dershowitz, Esq., New York, New York.

MEMORANDUM DECISION

CHIN, D.J.

***1** At a conference held on November 4, 1997, defendants Zola Mashariki and Natosha Reid Robinson requested access to a statement executed by defendant Janine Gilbert as part of a settlement of plaintiff William Griffin's claims against her, and then filed under seal. While Gilbert consented, plaintiff objected. Over plaintiff's objection, I ordered that the statement be shown to counsel for Mashariki and Reid Robinson, subject to the entry of an appropriate stipulation and order of confidentiality, without prejudice to defendants' right to later request a copy of the statement. Plaintiff's counsel requested the opportunity to object in writing even to this limited disclosure. I stayed my order and afforded all counsel the opportunity to make their respective arguments in writing. Since that time, I have received submissions on behalf of plaintiff and defendants Mashariki and Reid Robinson and I have reviewed *in camera* the sealed statement.

BACKGROUND

By stipulation executed on behalf of Griffin and Gilbert on October 21, 1997 and so ordered by this Court on November 11, 1997, plaintiff agreed to dismiss his claims against Gilbert with prejudice. Gilbert, in turn, made a written statement, filed under seal, and agreed with Griffin that:

The Statement shall not be made available or accessible to, or copied by, any person except upon application by Griffin or Gilbert, with notice to the other party, upon a showing of good cause, and upon such terms as the Court deem appropriate.

(Stipulation ¶ 2).

By letter dated November 7, 1997, Griffin objects to Mashariki's application on the grounds that she has no standing under the stipulation to apply for access to the statement, and that in any event, she has not made a showing of "good cause." By letter dated November 18, 1997, defendant Mashariki argues that Gilbert is likely to be a witness in this defamation action, and that her statement may bear on damages, witness credibility, and the absolute and relative liability of the various defendants. By separate letter dated November 18, 1997, defendant Reid Robinson argues that access to the statement will facilitate settlement with respect to her. Of course, both defendants are somewhat hindered by the fact that they can only speculate as to the contents of the statement.

DISCUSSION

Rule 26 of the Federal Rules of Civil Procedure sets the general standards for discovery:

Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action .... The information sought need not be admissible at trial if the informa-

tion sought appears reasonably calculated to lead to the discovery of admissible evidence.

Settlement-related information, including settlement agreements, are governed by the same rule and are discoverable without a heightened showing of relevance. *See, e.g.,* Salgado v. Club Quarters, Inc., No. 96 Civ. 383, 1997 WL 269509, at *1 (S.D.N.Y. May 20, 1997); *Collister Alley Music, Inc. v. Warner Bros. Records Inc.,* No. 96 Civ. 1762, 1997 WL 198081, at *1 (S.D.N.Y. April 22, 1997); *Tribune Co. v. Purcigliotti,* No. 93 Civ. 7222, 1996 WL 337277, at *1-2 (S.D.N.Y. June 19, 1996); SEC v. Thrasher, No. 92 Civ. 6987, 1996 WL 94533, at *1-2 (S.D.N.Y. Feb.27, 1996); *Bank Brussels Lambert v. Chase Manhattan Bank, N.A.,* Nos. 93 Civ. 5298, 93 Civ. 8270, 1996 WL 71507, *2-4 (S.D.N.Y. Feb.20, 1996); *cf.* Bottaro v. Hatton Assocs., 96 F.R.D. 158, 160 (E.D.N.Y.1982).

***2** Rule 408 of the Federal Rules of Evidence precludes the use of settlement-related materials as a means of establishing or disproving liability, but expressly allows for the use of such materials at trial for certain purposes, including impeachment. Notably, Rule 408 does not limit disclosure of settlement materials during discovery. *See* Weissman v. Fruchtman, No. 83 Civ. 8958, 1986 WL 15669, at *19 (S.D.N.Y. Oct.31, 1996). Nevertheless, a party seeking production must show relevance under Federal Rule of Civil Procedure 26.

The reasons advanced by defendants here are persuasive and sufficient to satisfy their burden under Rule 26. A statement made by a co-defendant to the plaintiff about the subject matter of the litigation-here, allegedly defamatory statements made by the defendants-is at least arguably relevant and alternatively is likely to lead to the discovery of admissible evidence. In addition, Gilbert's statement may well be impeachment material that either or both sides would seek to use in the likely event that Gilbert is a witness. *See* Tribune Co., 1996 WL 337277, at *2-3 (ordering production of settlement-related documents relevant to bias of witness); Thrasher, 1996 WL 94533, at *3 (ordering disclosure of settlement discussions proposed to be used for impeachment purposes).

Defendant Reid Robinson's argument that disclosure of the statement will facilitate settlement of her case because she is similarly situated to Gilbert does not provide a proper basis for disclosure, except in the sense that full disclosure generally promotes realistic case assessment. Relevance, not simply promotion of settlement, must be the touchstone. Defendant Reid Robinson is nonetheless entitled to discovery of Gilbert's statement for the same reasons as defendant Mashariki.

Plaintiff does not contest the relevance of the statement, nor does he argue that the statement is protected by any privilege. Rather, he expresses "vigorous objection[]" and "profound disturb[ance]" at the Court's purported "casual assent" to defendants' requests for access, and opposes such access on the grounds that (1) the settlement stipulation governs who has standing to request access to the statement and the standard to be applied in evaluating such requests, and (2) defendant Mashariki does not have standing and has not shown the "good cause" required. Plaintiff's arguments under the stipulation are irrelevant to the applications before me. Parties to a litigation cannot modify the Federal Rules of Civil Procedure by stipulation. More specifically, the mere fact that the settling parties agreed to maintain the confidentiality of part of the settlement, Gilbert's statement, cannot serve to shield that statement from discovery. *See* Tribune, 1996 WL 337277, at *3 (citing Weissman, 1986 WL 15669, at *19 ("The intention of the parties to the agreement, even if reflected in a confidentiality clause ... is not controlling.")); Magnaleasing, Inc. v. Staten Island Mall, 76 F.R.D. 559, 562 (S.D.N.Y.1977) (confidentiality clause held no barrier to discovery of relevant portions of settlement agreement).

***3** I am sensitive, however, to the plaintiff's expectation that Gilbert's statement would remain confidential. Accordingly, at this stage of litigation, disclosure of the statement shall be limited to a review by counsel for defendants Mashariki and Reid Robinson. The parties shall enter into an appropriate confidentiality stipulation and agreement limiting disclosure of the contents of the statement to defendants Mashariki and Reid Robinson and their counsel. Plaintiff need not produce a copy of the statement to defendants or their counsel at this time. Either defendant, however, may renew her application for a copy of the statement at a later time, should she wish.

SO ORDERED.

S.D.N.Y.,1997.
Griffin v. Mashariki
Not Reported in F.Supp., 1997 WL 756914 (S.D.N.Y.)

END OF DOCUMENT

EXHIBIT 5

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. and ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	**Case No. 3:09-CV-03235 (FLW-DEA)** **DEFENDANTS' NONINFRINGEMENT AND INVALIDITY CONTENTIONS**

Defendants Orchid Chemicals & Pharmaceuticals Ltd. and Orgenus Pharma Inc. (collectively "Orchid"), pursuant to this Court's Scheduling Order (D.I. 27) and the Local Patent Rules, herein sets forth its initial contentions relating to the noninfringement and invalidity of U.S. Patent No. 6,274,171, U.S. Patent No. 6,419,958, and U.S. Patent No. 6,403,120. Orchid reserves the right to supplement and/or revise these contentions as discovery in this case proceeds. For example, Orchid has requested and Wyeth has agreed to produce documents relating to the twelve earlier cases involving these patents. Those documents should have been produced several weeks ago. However, Wyeth has failed to produce even a single document. Orchid therefore reserves the right to supplement and/or revise these initial contentions and claim charts as discovery proceeds in this case.

I. THE CLAIMS OF THE '171, '120 AND '958 PATENTS ARE NOT INFRINGED BY ORCHID'S PROPOSED VENLAFAXINE CAPSULE PRODUCT

A. Analysis of the '171, '120, and '958 Patents

The '120 patent issued from a continuation of the application that issued as the '958 patent. The application that issued at the '958 patent is a divisional of the application that issued as the '171 patent. The '171, '120, and '958 patents share an essentially identical specification. When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 978 (Fed. Cir. 1999); *Jonsson v. The Stanley Works*, 903 F.2d 812, 817-18 (Fed. Cir. 1990). Thus, claim terms common to the claims of the '171, '120, and '958 patents should be construed to have the same meaning in all three of the patents.

1. The Claims of the '171 Patent

The '171 patent issued on August 14, 2001 and contains 25 claims. The independent claims, claims 1 and 20-25, are provided below.

1. An extended release formulation of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.

20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

21. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four

to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

22. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

24. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

25. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

2. The Claims of the '120 Patent

The '120 patent issued on June 11, 2002 and contains one independent claim, which is provided below.

1. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

3. The Claims of the '958 Patent

The '958 patent issued on July 16, 2002 and contains 6 independent claims, which are provided below.

1. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

2. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

3. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

4. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

5. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

6. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides

a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

4. The Common Disclosure

The '171, '120, and '958 patents share the same specification. Therefore reference is made to the '171 patent specification, which is equally applicable to the '120 and '958 patents.

The '171 patent notes in the "Background Of The Invention" that the administration of venlafaxine[1] as a rapid release compressed tablet is known for treating depression. '171 patent at col 1, lines 59-66. The specification explains that therapeutic dosing with such rapid release tablets results in an undesirable rapid increase in blood plasma levels of the active compound shortly after administration, which is followed by a decrease in blood plasma levels over several hours as the active compound is eliminated or metabolized. '171 patent at col 1, line 59-col 2, line 7. Subtherapeutic plasma levels are approached after about twelve hours following administration, thus requiring additional dosing with the drug. *Id.*

Also in the "Background Of The Invention" the '171 patent acknowledges that it is conventional in the drug industry to prepare encapsulated drug formulations which provide extended or sustained release properties. '171 patent at col 1, lines 35-38. Such extended release capsule dosage forms may be formulated by mixing the drug with one or more binding agents, moistened, extruded, and transformed into spheroids using standard spheronization equipment. The spheroids may then be film-coated to retard dissolution and placed in pharmaceutically acceptable capsules. *Id.* at col 1, lines 38-52. The specification notes that U.S. Pat. No. 4,138,475 discloses a sustained release pharmaceutical composition consisting of a hard gelatin capsule filled with film-coated spheroids comprised of the active ingredient propanolol in admixture with microcrystalline cellulose wherein the film coating is composed of ethyl cellulose, optionally, with hydroxypropylmethylcellulose and/or a plasticizer. '171 patent at col 1, lines 52-58.

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[1] Reference to "venlafaxine" means or includes "venlafaxine hydrochloride" unless otherwise indicated.

The specification alleges that "[n]umerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies." '171 patent at col 4, lines 60-64. This alleged problem was solved according to the specification by the addition of "hydroxypropylmethylcellulose 2208" to a mixture of venlafaxine and microcrystalline cellulose and followed by granulation, extrusion, transformation into spheroids, and coating. '171 patent at col 5, lines 1-28.

The specification states that the "formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose." '171 patent at col 2, line 63-col 3, line 2; Abstract. The specification further states the "extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose to provide the desired level of coating ...." '171 patent at col 4, lines 9-16. In addition, the specification states "the extended release spheroid formulations of this invention comprise from about 6 to about 40 percent venlafaxine hydrochloride, from about 50 to about 94 percent microcrystalline cellulose, NF, optionally, from about 0.25 to about 1 percent hydroxypropylmethylcellulose, and from about 2 to about 12 percent, preferably about 3 to 9 percent, film coating." '171 patent at col 6, lines 15-21.

5. Prosecution History

The '171, '120 and '958 patents include a priority claim to two non-provisional applications and one provisional application.

a. **Application No. 08/821,137**

Application No. 08/821,137 was filed on March 20, 1997, claiming priority to provisional application No. 60/014,06 filed on March 25, 1996. As filed, the '137 application originally contained 10 claims. Claims 1-5, 7, and 8 were directed to extended release formulations of venlafaxine, claim 6 was directed to a film coating, and claims 9 and 10 were method of use claims. Claims 1, 9 and 10, as filed, are provided below.

1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropyl methylcellulose coated with ethyl cellulose and hydroxpropylmethylcellulose.

9. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

10. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

In a July 30, 1997 interview with Examiner Hulina, the applicant agreed to amend claims 9 and 10 to depend from claim 1 in order to avoid a rejection over U.S. Patent No. 5,506,270. Thus, the applicant agreed to amend independent claims 9 and 10 to recite that the methods comprises administering "the encapsulated, extended release formulation of claim 1." It was also agreed that claim 6, drawn to a film coating, would be non-elected and cancelled. As a result of the amendments to the claims, Examiner Hulina allowed the application. However, the applicant did not pay the Issue Fee and the application went abandoned.

b. **Application No. 08/964,328**

Continuation-in-part application No. 08/964,328 was filed on November 5, 1997. The '328 application as originally filed contained a total of 18 claims. Original claims 1, 13, and 14 were the same as original claims 1, 9 and 10, respectively, in the parent '137 application.

In a first Office Action, a new examiner, Examiner Spear, allowed claims 11, 13, and 14. The Examiner rejected claim 1 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,138,475 in view of U.S. Patent No. 5,552,429. The Examiner asserted that the '475 patent showed a hard gelatin capsule comprised of spheroids coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. The Examiner cited the '429 patent as describing extended release dosage forms that included the drug venlafaxine.

In an April 13, 1999 response, the applicant canceled claim 1, amended claim 2 to be in independent form, and added new claims 19-26. In response to the rejection of claim 1 under 35 U.S.C. §103(a), the applicant noted that claim 1 had been canceled and replaced by new claim 23 (limited to coated spheroids comprising venlafaxine, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose, and being coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose). The applicant argued that the '429 patent did not provide extended release compositions of venlafaxine, and instead only described particular sustained release compositions for pindolol. The applicant argued that the combination of references did not suggest the claimed subject matter. The applicant further argued that new claims 19-22 are dependent upon allowable claims 15, 2, 13, and 14, respectively, and are therefore allowable also.

The Examiner issued a further Office Action rejecting claims 23-26 under 35 U.S.C. §103(a) relying upon the '475 patent in view of the '429 patent. The applicant allowed the '328 application to go abandoned without filing a response to the Office Action.

c. The '171 Patent

Continuation-in-part application No. 09/488,629 was filed on January 20, 2000. This application issued as the '171 patent.

The '629 application was originally filed with 21 claims. Independent claim 1 recited an encapsulated, extended release formulation of venlafaxinc comprising spheroids comprised of venlafaxine, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose, coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. Original independent claims 21 and 22, which ultimately issued as claims 20 and 21 of the '171 patent, were similar to claims 9 and 10 in the grandparent '137 application.

In a first Office Action, Examiner Spear allowed claims 21 and 22, and rejected claim 1 under 35 U.S.C. §103(a) as being unpatentable over the '475 patent in view of the '429 patent. In response, the applicant canceled claim 1, amended claim 2 to be in independent claim form (claim 2 ultimately issuing as claim 1 of the '171 patent), and added new claims 23-26 (which issued as claims 22-25 of the '171 patent). The Examiner allowed the amended claims and the '171 patent issued on August 14, 2001.

d. The '958 Patent

Divisional[2] application No. 09/884,412 was filed on June 19, 2001. This application issued at the '958 application.

The '412 application was originally filed with three independent claims, claims 1, 23 and 24. Claim 1 recited an encapsulated, extended release formulation of venlafaxine comprising spheroids comprised of venlafaxine, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose, coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. Original claims 23 and 24 were substantially similar to

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[2] The '412 application was incorrectly referred to as a divisional application. However, it is not a divisional application because no restriction requirement was issued in the prior '629 application. *See*, *e.g.*, 201.06.

claims 9 and 10 as filed in the '137 application, and issued as claims 1 and 2 in the '958 patent.

In a first Office Action, Examiner Spear rejected claims 23 and 24 for obviousness-type double patenting over claims 20 and 21 of the '171 patent. The Examiner noted that while the claims of the '171 patent required an encapsulated dosage form, unencapsulated forms would have been obvious. Claim 1 was rejected under 35 U.S.C, §103(a) as obvious over the '475 patent in view of the '429 patent.

In response, the patentee canceled claim 1, added new claims 25-28 (which issued as claims 3-6), and submitted a terminal disclaimer with respect to the '171 patent. In submitting the terminal disclaimer, the patentee alleged that the claims of the '958 patent were not limited to unencapsulated spheroids.

The Examiner allowed the claims and the '958 patent issued on July 16, 2002.

e. **The '120 Patent**

Continuation application No. 09/950,965 was filed September 12, 2001. The '965 application issued as the '120 patent.

The '965 application was filed with 13 claims (claims 1 and 23-34), with claims 1 and 23 being independent claims. Claim 1 recited an encapsulated, extended release formulation of venlafaxine comprising spheroids comprised of venlafaxine, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose, coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. Original claim 23, which issued as claim 1 in the '120 patent, was substantially similar to claims 9 and 10 filed in the '137 application.

In a first Office Action, Examiner Spear rejected claim 1 under 35 U.S.C. §103(a) as obvious over the '475 patent in view of the '429 patent, allowed claim 23, and objected to original claims 24-34.

In response, the patentee canceled claim 1, amended the dependency of claims 24 and 25, and added new claims 35 and 36 (which issued as claims 13 and 14). The Examiner allowed the claims and the '120 patent issued on June 11, 2002.

B. Claim Construction

The District Court of New Jersey previously construed the claims of the '171, '120, and '958 patents. Wyeth v. Teva, 03-cv-1293 (D.N.J. 2005). Under this Court's construction of the claim terms "extended release formulation," "spheroid," and "with diminished incidence(s) of nausea and emesis" Orchid's proposed venlafaxine ANDA products do not infringe any claim of the '171, '120, and '958 patents for at least the following reasons.

1. Extended Release Formulation

As properly construed, the claim term "extended release formulation" means a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose (HPMC), coated with a mixture of ethyl cellulose and HPMC, wherein the formulation is able to provide in a single daily dose a therapeutic blood serum level of venlafaxine over a 24 hour period. Orchid's proposed venlafaxine hydrochloride extended release capsule product lacks both microcrystalline cellulose and hydroxypropylmethylcellulose or their equivalents, such that Orchid's ANDA filing does not constitute an act of infringement, nor would the marketing, use, or sale of any product covered by that ANDA.[3]

The inventors defined "extended release formulation" several times in the specification. In the abstract, they disclosed:

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[3] As a matter of law, Orchid would not directly infringe any of the method claims, regardless of what claim construction the Court ultimately adopts because Orchid does not and will not directly administer its proposed products to patients. *See Warner-Lambert Co. v. Apotex*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (sale and distribution of pharmaceutical products cannot constitute direct infringement of a method claim). Orchid would not induce infringement of any method claim because there would be no direct infringement by another and in addition it lacks the specific intent to encourage another's infringement. Orchid would not contributory infringe any method claim because there would be no direct infringement by another and Orchid's product is capable of substantial noninfringing uses under any possible construction of the claims.

> More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlfaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent at Abstract. The inventors reiterated this same restrictive definition in the "Brief Description of the Invention:"

> The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, col. 2, line 62-col. 3, line 2. After setting forth the foregoing description of their invention, the inventors go on to address the preferred embodiments of their invention. *See* '171 patent, col. 3, lines 5-62. Notably, in the "Detailed Description of the Invention," the inventors again defined "extended release formulations":

> The extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating . . . .

'171 patent, col. 4, lines 9-15.

Thus, the inventors acted as their own lexicographers and limited the meaning of "extended release formulation" to mean a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose (HPMC), coated with a mixture of ethyl cellulose and HPMC, wherein the formulation is able to provide in a single dose a therapeutic blood serum level of venlafaxine over a 24 hour period. *See Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-40 (Fed. Cir. 2004); *Wyeth v Teva Pharmaceuticals USA, Inc.*, 03-CV-1293 (WJM), 2005 U.S. Dist. LEXIS 20034 (D.N.J. Sept. 6, 2005).

Further, the specification distinguishes the "extended release formulations" of the invention from hydrogel extended release formulations. The specification discloses that the inventors' attempts to develop extended release hydrogel tablets were "fruitless," teaching one of

ordinary skill that it is not possible to achieve the desired dissolution rates using hydrogel technology. *See* '171 patent at col. 4, lines 60-64 and col. 10, lines 53-57. These statements are made without qualification. Accordingly, one of ordinary skill in the art would understand the term "extended release formulation" to mean a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose (HPMC), coated with a mixture of ethyl cellulose and HPMC, wherein the formulation is able to provide in a single, daily dose a therapeutic blood serum level of venlafaxine over a 24 hour period. *See Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed.").

The specification repeatedly and uniformly describes the "extended release formulations of this invention" as venlafaxine in admixture with microcrystalline cellulose and HPMC, formed into spheroids, and coated with ethyl cellulose and HPMC. When viewed in the context of the specification, the term "extended release formulation" would be construed by one of ordinary skill in the art to include these specific ingredients and structures. *See ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 2009 U.S. App. LEXIS 5271, *7-8 (Fed. Cir. Mar. 13, 2009). The unequivocal language the inventors used when describing their invention—"the invention comprises an extended release formulation of," "the formulations of this invention comprise," and "the extended formulations of this invention are"—rebuts any presumption that may be established by the doctrine of claim differentiation. *ICU Medical*, 2009 U.S. App. LEXIS 5271 at *11; *Kraft Foods, Inc. v. Int 'l Trading Co.*, 203 F.3d 1362, 1368-69 (Fed. Cir. 2000) (finding the presumption of claim differentiation overcome because the specification and prosecution history described the "protecting back panel" as one that must be relatively stiff). Though Wyeth may contend that the foregoing construction renders certain dependent claims coterminous and certain claim limitations superfluous, that result is appropriate where, as here, the inventors acted as their own lexicographers. *See Multiform Desiccants, Inc. v. Medzam. Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("The doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."); *Sule v. Kloehn Co., Ltd.*, 149 F.Supp. 2d 115, 128 (D.N.J. 2001) ("Claim differentiation is a guide, not a rigid rule. If a claim will bear only one interpretation, similarity will have to be tolerated.") (quoting *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 404 (Ct. Cl. 1967)); *Wyeth*, 2005 U.S. Dist. LEXIS 20034 at *11-*12.

Further, the specification distinguishes formulations not containing microcrystalline cellulose and hydroxypropylmethylcellulose and also distinguishes formulations containing certain binders, such as polyvinylpyrrolidone, methylcellulose, water, and polyethylene glycol ('171 patent at col 5, lines 1-13) and distinguishes hydrogel formulations ('171 patent at col 4, lines 57-64). The specification indicates that such formulations resulted in "failed experiments." '171 patent at col 6, line 6. The specification distinguishes such "failed" formulations from the claimed formulations comprising microcrystalline cellulose and hydroxypropylmethylcellulose. Thus, the patentee has acknowledged that formulations comprising microcrystalline cellulose and hydroxypropylmethylcellulose are substantially different from formulations lacking these excipients.

2. With diminished incidence(s) of nausea and emesis

The claim term "with diminished incidence(s) of nausea and emesis" is properly interpreted to mean a statistically significant decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day.

The claims do not use level or degree; rather, they only refer to "incidence." The inventors drew a distinction between "level" and "incidence." Although the specification refers to both terms, the claims only recite "incidence." The inventors meant to differentiate between the two terms. It is clear from the specification that when the inventors wanted to refer to "incidence," they did. Thus, the term "incidence" is properly limited to its ordinary meaning as informed by the specification.

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, ***the level of nausea and incidence of emesis*** that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, ***the probability of developing nausea*** in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for ***reducing the level of nausea and incidence of emesis*** attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

'171 patent at col. 2, lines 45-62 (emphasis added).

The word "level," as used in the above passage, connotes degree. The passage above also distinguishes between "level," *i.e.*, degree, and "incidence," *i.e.*, frequency. The passage makes clear that the inventors were concerned with the number of patients experiencing side effects, not necessarily the severity of those side effects. Moreover, the abstract states that the invention "provides a lower incidence of nausea and vomiting than the conventional tablets." '171 patent at Abstract. Because the only discussion of the conventional tablets in the specification that is relevant to the term "incidence" concerns the percent of patients that experienced side effects, the abstract supports a narrow construction.

The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 908 (Fed. Cir. 2004). Thus, the fact that the patent specification may discuss a reduced "level" and "incidence" of nausea does not require that claims using the word "incidence" encompass both benefits. In addition, the "incidence" limitation is not present in all of the asserted claims. *See, e.g.*, '171 patent at claims 21, 24-25; '958 patent at claims 2, 5-6.

Thus, the subject claims require that the "extended release formulation" result in a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day. There is no evidence in the prescribing information for Effexor XR® that daily doses of between 75 mg and 225 mg of Effexor XR® result in a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day. By law, Orchid must duplicate most portions of the Effexor XR® prescribing information in its own prescribing information. *See, e.g.*, 21 U.S.C. § 355(j)(2). Thus, the prescribing information for Orchid's proposed venlafaxine hydrochloride extended release capsule product will contain no indication that use of its proposed product will result in a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day.

Moreover, Orchid's venlafaxine hydrochloride extended release capsule product will have a substantially different formulation than the Effexor XR® product and will exhibit significantly different pharmacokinetic parameters. Thus, the incidences of nausea and vomiting resulting from administration of Orchid's proposed venlafaxine hydrochloride extended release capsule product cannot be predicted from the Effexor XR® prescribing information. Indeed, as stated in the Effexor XR® prescribing information, "these figures cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses and investigators." *See* Effexor XR® prescribing information at p. 30. For these reasons, the claims of the '171, '120, and '958 patents are inapplicable to and do not cover Orchid's proposed venlafaxine hydrochloride extended release capsule product, nor would Orchid's prescribing information induce any third party to infringe any method claim of the '171, '120, and '958 patents. In addition, neither Orchid's proposed venlafaxine hydrochloride extended release capsule product nor its use would infringe any dependent claim of the '171, '120, and '958 patents because no dependent claim can be infringed if the independent claim from which it depends is not infringed. *Pfizer Inc. v. Ranbaxy Labs.*, 457 F.3d 1284 (Fed. Cir. 2006).

3. Spheroid

Orchid's proposed venlafaxine ANDA product will not meet at least the "spheroid" claim limitation. In the context of the asserted patents, one of ordinary skill in the art would understand that drug particles are prepared in several different ways. *See*, *e.g.*, Pharmaceutical Dosage Forms: Tablets, vol 3, 2nd Ed., Lieberman et al. eds., 1990, Marcel Dekker Inc. at pp. 217-221. A compaction process is used to form tablets. *Id.* A surface layering process is used to form pellets. *Id.* An agglomeration process is used to form granules. And an extrusion-spheronization process is used to form spherical pellets. *Id.* The advantages of the extrusion-spheronization process include: (1) production of the spherical pellets without using seeds, leading to reduction the bulk of final product; (2) the ability to regulate size of the pellets within a narrow particle size distribution; (3) the ability to produce high-density, low-friability, spherical pellets; and (4) the ability to achieve excellent surface characteristics for subsequent

coating, leading to an homogeneous distribution of coating material(s) onto the spherical pellets. *Id.*

The specifications of the asserted patents state that the desired dissolution rates of the sustained release dosage forms of venlafaxine hydrochloride were impossible to achieve except "with the film-coated spheroid composition of this invention." *See*, *e.g.*, '171 patent at 10:53-57. Every use of the term "spheroid" in the specifications is in the context of having been prepared by an extrusion-spheronization process. *See*, *e.g.*, '171 patent at 5:1-13 and 6:6-11. Thus, although one of ordinary skill in the art would know that "spherical-shaped pellets" could be prepared by a surface layering process or an agglomeration process, they would understand that the term "spheroid" used in the asserted patent referred only to the high-density, low-friability, spherical pellets having a narrow size distribution as can only be achieved by the extrusion-spheronization process. One of ordinary skill in the art would understand that the term "spheroid" did not include granules, beads, and pellets, such as those obtained by the surface layering or agglomeration processes. Indeed, the specification distinguishes between beads and spheroids ('171 patent at 4:13), and states that the granulation process is only used to make an extrudate that was spheronized. *See*, *e.g.*, '171 patent at 5:1-13. Orchid's proposed products do not contain "spheroids," but instead contain "pellets." *See*, *e.g.*, ORC-VEN000724-728. "Pellets" are distinct from "spheroids," which, for example, are spheronized. *See*. *e.g.*, the '171 patent at 5:1-28.

A claim chart identifying each claim of the asserted patents for which claim limitation(s) are literally absent from Orchid's proposed venlafaxine products or literally absent from the use of Orchid's proposed venlafaxine products is attached hereto as Appendix A.

II. THE CLAIMS OF THE '171, '120 AND '958 PATENTS ARE INVALID

If the claim constructions above are not adopted and one of Wyeth's alternative claim construction proposals is adopted, then the claims of the '171, '120, and '958 patents would be invalid for being anticipated by and/or obvious over the prior art. Further, the claims would be invalid as indefinite and not enabled.

A. Anticipation and Obviousness

The claims of the '171, '120, and '958 patents are invalid under 35 U.S.C. §§ 102 and/or 103 as being anticipated by, or obvious in light of, the prior art. The '171, '120, and '958 patents all stem from the same provisional application (Application No. 60/014,006), filed on March 25, 1996. As detailed below, prior art available before the date of March 25, 1996, in combination with the knowledge of a person of ordinary skill in the art, renders all of the claims of the '171, '120, and '958 patents obvious and/or anticipated.

The claims of the subject patents generally are directed to a method of administering venlafaxine as an extended release formulation that provides a therapeutic blood plasma concentration over a 24 hour period with diminished incidence of nausea and emesis and a T_{max} of various specified periods from about 4 to about 8 hours ('171 patent claims 20, 22, and 23 and '958 patent claims 1, 3, and 4); provides a therapeutic blood plasma concentration over a 24 hour period with diminished incidence of nausea and emesis and a C_{max} of no more than about 150 ng/ml ('120 patent claims 1-14); or provides a peak blood plasma level of venlafaxine in various specified periods from about 4 to about 8 hours and eliminates the troughs and peaks of drug concentration in patient blood plasma ('171 patent claims 21, 24, and 25 and '958 patent claims 2, 5, and 6). Claim 1 of the '171 patent recites an extended release formulations having various specified levels of microcrystalline cellulose and hydroxypropylmethylcellulose ('171 patent claims 1-19).

The specification acknowledges that it was known that administration of venlafaxine in a compressed tablet required dosing two or three times a day because the rapid dissolution from the compressed tablets resulted in a rapid increase of blood plasma levels of the active compound followed by a decrease to subtherapeutic levels about 12 hours after administration. '171 patent at col 1, line 59-col 2, line 11. The specification also acknowledges that "[e]xtended release drug formulations are conventionally produced as compressed tablets by hydrogel tablet technology." '171 patent at col 1, lines 12-14. It also acknowledges that where the production of such hydrogel tablets is not feasible, "it is conventional in the drug industry to prepare encapsulated drug formulations which provide extended or sustained release properties." '171 patent at col 1, lines 35-38. As an example of the conventional encapsulated drug formulations, the specification notes that U.S. Pat. No. 4,138,475 discloses a sustained release pharmaceutical

composition consisting of a hard gelatin capsule filled with film-coated spheroids comprised of propanolol in admixture with microcrystalline cellulose wherein the film coating is composed of ethyl cellulose, optionally, with hydroxypropylmethylcellulose and/or a plasticizer. '171 patent at col 1, lines 52-58.

The specification asserts that "[n]umerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies." '171 patent at col 4, lines 60-64. The specification also alleges that attempts to produce encapsulated drug formulations "failed" unless "hydroxypropylmethylcellulose 2208" was added to venlafaxine and microcrystalline cellulose to make spheroids. '171 patent at col 5, lines 1-13. Thus, the specification states that the "extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating ...." '171 patent at col 4, lines 9-16.

Obviousness is evaluated following the *Graham* test as elaborated on in *KSR*. The factors are: (1) "the scope and content of the prior art"; (2) the "differences between the prior art and the claims"; (3) "the level of ordinary skill in the pertinent art"; and (4) "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc." *KSR*, 127 S. Ct. at 1734.

1. The Level of Ordinary Skill in the Art

A person of ordinary skill in the art is a hypothetical person who at the time of the invention has either a Ph.D. in a field related to pharmaceutical formulation and processing or a similar Masters or undergraduate degree and at least several years of experience in pharmaceutical formulation.

2. The Scope and Content of the Prior Art

U.S. Patent No. 5,506,270 teaches that venlafaxine is effective for treating depression and for treating hypothalamic amenorrhea. '270 patent at col 1, lines 16-25 and col 2, line 62-col 3, line 67. (*See also*, U.S. Patent Nos. 4,535,186; 5,530,013; 5,552,429; 5,916,923; 6,440,457.) The '270 patent teaches that the preferred dosage forms are tablets and capsules. *Id.* at col 4, lines 56-57. The patent teaches that the maximum daily dose for venlafaxine is about 225 mg. *Id.* at col 5, lines 4-5. The '270 patent indicates that venlafaxine may be administered in divided daily doses or administered as a "sustained oral administration form or time-release form, which may be used to spread the dosage over time, such as for once-a-day applications." *Id.* at col 5, lines 1-4 and col 5, lines 25-27. European Patent No. 639,374 also teaches that conventional tablets of venlafaxine are administered two or three times a day and that sustained release formulations of venlafaxine for once-a-day administration are favored. It was well-known in the prior art that the use of rate-controlled or sustained-release formulations resulted in (1) a reduction in drug blood level fluctuations, (2) reduction in dosing frequency, (3) enhanced patient convenience and compliance, (4) reduction in adverse side effects, and (5) reduction in healthcare costs. *See, e.g., Pharmaceutical Dosage Forms and Drug Delivery*, H. C. Ansel et al. eds., 6th Ed, 1995 at 213, 215 ("Pharmaceutical Dosage Forms").

Venlafaxine was known to be safe and effective for long-term treatment of major depression at daily doses from 75 to 225 mg given t.i.b. *See, e.g.*, R. Shrivastava et al., J. *Clin. Pharmacol.*, 1994, 14, 322 ("Shrivastava") and the Physicians' Desk Reference, 49th ed. (1995). Goodnick, *Clin. Pharmacokinet.*, 1994, 27, 307 ("Goodnick") teaches that conventional tablets of venlafaxine have a relatively short T_{max} value, which may relate to the early onset of adverse effects. *Id.* at 308. Goodnick also teaches that venlafaxine has a half life of 2.7 to 3.8 hours, and that a drug with a half life much shorter than 24 hours may result in reduced compliance because the drug will need to be administered in multiple daily doses. *Id.* at 324, 309. K. Klamerus et al., *J. Clin. Pharmacol.*, 1992, 32, 716 ("Klamerus") discloses that the side effects, such as nausea and emesis, were most frequent after administration of the highest doses of venlafaxine. Klamerus discloses that a 25 mg dose of venlafaxine resulted in C_{max} of 37 ng/ml, t_{max} of 2.4 h, and $t_{1/2}$ of 2.7 h; that a 75 mg dose of venlafaxine resulted in C_{max} of 102 ng/ml, t_{max} of 2.1 h, and $t_{1/2}$ of 3.5 h; and that a 150 mg dose of venlafaxine resulted in C_{max} of 163 ng/ml, t_{max} of 2.1 h,

and $t_{1/2}$ of 3.8 h. *Id.* at 720, Table I. For the maximum daily dose for outpatient therapy of 225 mg/day (75 mg t.i.d.), Klamerus reports that C_{max} was 167 ng/ml. *Id.* at 722, Table II. For the minimum daily dose of 75 mg/day (25 mg t.i.d.) Klamerus reports that C_{max} was 53 ng/ml. *Id.* at 722, Table II.

International publication WO 94/27589 teaches that a critical need exists for an extended release dosage form for venlafaxine. '589 publication at 3. The publication teaches that the conventional dosage forms for venlafaxine require dosing twice or three times per day, which produces peaks and valleys in blood plasma concentration. *Id.* The publication teaches that there are several inherent problems in such multiple dose therapy:

> For example, if the dosing interval is not appropriate for the biological half-life of the drug, large peaks and valleys may result in the drug blood levels. Also, the drug blood level may not be within the therapeutic range at sufficiently early times, an important consideration for many disease states. And too, patient noncompliance with the multiple dosing regimen can result in a failure of this approach, especially as a drug in circulation surges to a high each time the drug is administered followed by a decline in drug concentration in the blood and in body compartments. Thus, a graph of drug in circulation following a dosage program of several doses, has an appearance of a series of peaks, which may surpass the toxic threshold.

Id. at 2. Its U.S. counterpart, U.S. Patent No. 6,440,457, claims a method of administering venlafaxine in a manner that anticipates claims 1-6 of the '958 patent, claims 20-25 of the '171 patent, and claims 1 and 2 of the '120 patent.

Gupta et al., in *Treatise On Controlled Drug Delivery*, A. Kydonieus ed., Marcel Dekker 1992 ("Gupta") reports that, in general, drugs with short half-lives (2-4 h) make good candidates for controlled release systems. *Id.* at 257. Gupta also reports that most controlled release formulations are dissolution-controlled, and that the drug release rate from the dosage form is the rate-limiting step. Gupta at 257. An important restriction to the use of oral extended release formulations is the limited residence time of the dosage form in the small intestine. *See, e.g.*, B. M. Silber et al., "Pharmacokinetic/Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at p. 216 ("Silber"). In general, the absorption rate for most drugs decreases as the dosage form moves beyond the jejunum. Gupta at 257. Moreover, once past the ileocecal junction, a variety of

factors generally reduce the drug absorption rate to below acceptable levels. *Id.* This creates a time limit of about 6-9 hours during which the drug can be delivered in a predictable manner. *Id.* Literature data suggests that 9-12 hours is a reasonable estimate of average effective absorption time after oral administration of a well-absorbed drug in a dosage form that remains intact in the gastrointestinal tract. Silber at 240. Thus, the dissolution half-life of an extended release formulation should not exceed 3-4 hours. *Id.*

The rate of absorption of a drug administered as a solid oral-dosage form is partly dependent upon its rate of dissolution in the gastrointestinal fluids. L. Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at 6. This factor is the basis for the so-called controlled-release, extended-release, sustained-release, or prolonged-action pharmaceutical preparations that are designed to produce slow, uniform absorption of the drug for 8 hours or longer. *Id.* at 6-7. Potential advantages of such preparations are reduction in the frequency of administration of the drug as compared with conventional dosage forms (possibly with improved compliance by the patient), maintenance of a therapeutic effect overnight, and decreased incidence and/or intensity of undesired effects by elimination of the peaks in drug concentration that often occur after administration of immediate-release dosage forms. *Id.* at 7. Controlled-release dosage forms are most appropriate for drugs with short half-lives (less than 4 hours). *Id.* at 7. Venlafaxine is reported to have a half-life of 3-4 hours, requiring administration in two or three divided does per day, which is a regimen that does not promote compliance. J. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at 6A-30S.

U.S. Patent No. 5,229,135 teaches a sustained-release formulation for the water-soluble drug diltiazem suitable for once daily administration. '135 patent at col 1, line 13 and col 2, lines 18-20. Diltiazem has a half-life of about 4 hours. *See, e.g.*, Goodman & Gilman's at 1736. The '135 patent provides the following recommended *in vitro* drug release profile as measured using a paddle apparatus according to U.S. Pharmacopeia XXII:

(a) from 15 to 40% of the total diltiazem is released after 4 hours of measurement;
(b) from 40 to 70% of the total diltiazem is released after 8 hours of measurement;
(c) from 50 to 85% of the total diltiazem is released after 12 hours of measurement; and
(d) from 70 to 100% of the total diltiazem is released after 24 hours of measurement.

'135 patent at col 4, lines 55-68.

Starting with limited data on a drug candidate for sustained release, such as dose, rate constants for absorption and elimination, some elements of metabolism and some physical-chemical properties of the drug, one can estimate a desired release rate for the dosage form, the quantity of drug needed, and a preliminary strategy for the dosage form to be utilized. H.-W. Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at p. 375 ("Hui"). The formulator will merely design a dosage form based on *in vitro* studies, test it in a human or animal model, and then modify the system according to these results. *Id.* at 375-76. Among the most common mechanisms utilized in rate-controlled pharmaceutical products is the solvent action of biologic fluids on coated drug particles. *Pharmaceutical Dosage Forms* at 216. Beads or granules of drug can be formed by coating non-pareil seeds or beads made of sugar and starch with a solution of the drug. Alternatively, the starting granules can contain the drug itself. *Id.* at 216. The beads or granules are then coated with a cellulosic material like ethylcellulose. *Id.* at 216; Hui at 377-79. The beads or granules of different thicknesses of coatings can be blended in various proportions to achieve the desired blood-level profile. *Id.* at 216. One of the most preferred fillers for use in making granules is microcrystalline cellulose. *Id.* at 194-6. As acknowledged in the '171 patent, extended release capsule dosage forms were known in the art prior to March 25, 1996. '171 patent at col 1, lines 34-58. U.S. Patent No. 4,138,475, referenced by the '171 patent, describes a sustained release capsule containing the water-soluble drug propranolol. The sustained release capsule is prepared by forming spheroids of propranolol and microcrystalline cellulose. The spheroids are coated with a mixture of ethylcellulose and hydroxypropylmethylcellulose and filled into hard gelatin capsules. *See* '475 patent at col 2, lines 20-53. In addition, U.S. Patent Nos. 5,552,429 and 5,916,923 disclose extended release formulations of venlafaxine, U.S. Patent Nos. 4,808,413; 4,837,030; 5,229,135; and 5,273,760 described spheroid, extended-release formulations and WO 92/01446 describes pellet, extended-release formulations that when combined make the claims of the asserted patents obvious.

3. Differences Between the Prior Art and the Claims

Prior to March 25, 1996, one of ordinary skill in the art would have known that thrice daily dosing of conventional venlafaxine tablets at from 75 to 225 mg per day was safe and effective for treatment of depression. They would have known that side effects were associated with higher doses of venlafaxine and that patient compliance was adversely impacted by the required twice or thrice daily dosing regimen. One of ordinary skill would have known that an extended release formulation could reduce side effects compared to the conventional formulation and that a once-daily, extended release formulation would increase patient compliance.

One of ordinary skill in the art would have been aware of several methods for preparing extended release formulations of venlafaxine. One such method would have been preparing particles of venlafaxine and coating them with a polymer such as ethylcellulose to slow the dissolution rate. One of ordinary skill would have known that microcrystalline cellulose was useful for mixing with water soluble active ingredients and making granules suitable for coating with ethylcellulose. One of ordinary skill would have known that by altering the composition and thickness of the coating a desired t_{max} and C_{max} could be achieved. One of ordinary skill would have been aware that the maximum recommended daily dose of 225 mg of venlafaxine produced a C_{max} of about 167 ng/ml and that the minimum recommended daily dose of 75 mg of venlafaxine produced a C_{max} of about 53 ng/ml. Thus, one of ordinary skill in the art would have targeted a C_{max} of less than about 167 ng/ml and greater than about 53 ng/ml for once-daily formulations of venlafaxine. One of ordinary skill in the art would have known that for an extended release formulation of venlafaxine the t_{max} would be increased from the 2 hour t_{max} of the conventional formulation. Indeed, the relatively short t_{max} of 2 hours for venlafaxine was thought to relate to the early onset of adverse effects, so one of ordinary skill in the art would have been motivated to delay it in an extended release formulation. One of ordinary skill in the art would have known that venlafaxine in an extended release dosage form should be released and absorbed in less than about 9-12 hours, and ideally less than about 6-9 hours for the most predictable absorption profile. One of ordinary skill would have been led to develop an extended release formulation of venlafaxine having a t_{max} greater than 2 hours and would have expected that the t_{max} of an extended release formulation would have been greater than 2 hours and less

than about 9 hours. Thus, all the elements of the claims of the '171, '120, and '958 patents were known to one of ordinary skill in the art.

Prior to March 25, 1996, one of ordinary skill in the art would have been motivated to design the extended release venlafaxine formulations of claims 1-19 of the '171 patent and use those formulations in the methods of claims 20-25 of the '171 patent, claims 1-14 of the '120 patent, and claims 1-6 of the '958 patent. The extended release dosage form of claims 1-19 of the '171 patent is the same extended release dosage form disclosed in the '475 patent, with the exception of the active ingredient. One of ordinary skill would have been motivated to replace the active ingredient propranolol with venlafaxine to develop a once-daily, extended release venlafaxine dosage form that is identical to or an obvious variation of the formulations described in claims 1-19 of the '171 patent. One of ordinary skill would have been motivated to coat the venlafaxine/microcrystalline cellulose spheroids with the appropriate amount of ethylcellulose or ethylcellulose/HPMC so that the coated spheroids exhibited a dissolution profile similar to the one described in the '135 patent, which is the same as or an obvious variation of the dissolution profile in claims 11 and 19 of the '171 patent. One of ordinary skill would also have been motivated to develop the extended release venlafaxine formulation to produce a C_{max} of about 150 ng/ml. One of ordinary skill in the art would have had a reasonable expectation of success in light of, *inter alia*, the teachings of the '475 patent and the other prior art discussed herein. Thus, claims 1-19 of the '171 patent are obvious in light of the prior art.

Method claims 20, 22, and 23 of the '171 patent and method claims 1, 3, and 4 of the '958 patent recite an extended release, once-daily dosage form that diminishes incidences of nausea and emesis and results in a t_{max} of about 4 to about 8 hours. Method claims 21, 24, and 25 of the '171 patent and claims 2, 5, and 6 of the '958 patent recite an extended release dosage form that eliminates the troughs and peaks of drug concentration and results in a t_{max} of about 4 to about 8 hours. One of ordinary skill would have been motivated to develop an extended release, once-daily formulation for venlafaxine because it was expected to result in (1) a reduction in drug blood level fluctuations, (2) a reduction in dosing frequency, (3) enhanced patient convenience and compliance, (4) a reduction in adverse side effects, and (5) a reduction in healthcare costs. They would have been motivated to develop a formulation that was substantially absorbed within 12 hours to ensure absorption of the drug in the GI tract, and

preferably within 9 hours for the most predictable absorption profile. For venlafaxine, one of ordinary skill in the art would have used routine bioavailability studies to compare different extended release formulations of venlafaxine to ascertain the one that produced the most desirable absorption pattern or relied on the dissolution profile described in the '135 patent or some other similar dissolution profile. One of ordinary skill in the art would have expected that the t_{max} for a once-daily, extended-release formulation for venlafaxine would be greater than the 2-3 hour t_{max} of the conventional tablet and less than about 9 hours. Thus, they would have expected a t_{max} of about 6 hours, plus or minus 3 hours for a once-daily, extended-release venlafaxine formulation. One of ordinary skill in the art would have had a reasonable expectation of success in light of, *inter alia*, the teachings of the '475 patent and the other prior art discussed herein. Thus, method claims 20-25 of the '171 patent and method claims 1-6 of the '958 patent are obvious in light of the prior art.

Method claims 1-14 of the '120 patent recite an extended release, once-daily dosage form of venlafaxine that diminishes incidences of nausea and emesis and results in a C_{max} of no more than about 150 ng/ml. One of ordinary skill would have been motivated to develop an extended release, once-daily formulation for venlafaxine because it was expected to result in (1) a reduction in drug blood level fluctuations, (2) a reduction in dosing frequency, (3) enhanced patient convenience and compliance, (4) a reduction in adverse side effects, and (5) a reduction in healthcare costs. The specific amounts of excipients and coatings described in the claims are either the same as or obvious variations of those taught in the '475 patent. One of ordinary skill in the art would have been motivated to develop a formulation with a C_{max} less than about 150 ng/ml because this is the C_{max} attained with multiple dosing at the maximum recommended daily dosage of 225 mg for venlafaxine and because a higher C_{max} was expected to increase side effects such as nausea and emesis. One of ordinary skill in the art would have had a reasonable expectation of success in light of, *inter alia*, the teachings of the '475 patent and the other prior art discussed herein. Thus, method claims 1-14 of the '120 patent are obvious in light of the prior at.

A claim chart identifying where specifically in each prior art reference each limitation of each asserted claim is found is attached hereto as Appendix B.

4. Secondary Considerations

There are no relevant secondary considerations regarding the '171, '120, and '958 patents for assessing obviousness. When performing an obviousness analysis, objective evidence of non-obviousness may be considered, if present. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Examples of objective criteria that are commonly used to rebut evidence of obviousness include commercial success, unexpected results, and a long-felt need. *See In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994); *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir 1990); *Stratoflex*, 713 F.2d at 1538-39.

a. Commercial Success

For evidence of commercial success to be given substantial weight, there must be a nexus between the evidence and the merits of the claimed invention. *Stratoflex*, 713 F.2d at 1539. A patentee offering objective evidence of non-obviousness bears the burden of demonstrating this "nexus." *See In re Paulsen*, 30 F3d at 1482. Specifically, the patentee must demonstrate "a legally and factually sufficient connection" between the evidence and the patented invention to demonstrate that the evidence does in fact corroborate the invention's non-obviousness. *See id.* Even if the commercial product Effexor XR® incorporates the alleged invention of claims the '171, '120, and '958 patents, any commercial success of this product does not have the required nexus to the alleged invention of these claims. For example, there is no indication that consumers purchase Effexor XR® because of a diminished incidence of nausea and emesis. Indeed, there is no evidence that Effexor XR® produces a diminished incidence of nausea and emesis. Similarly, there is no evidence that consumers purchase Effexor XR® due to the elimination of peaks and troughs, a C_{max} of less than about 150 ng/ml, or a t_{max} of between about four to about 8 hours. Any commercial success is a result of the combination of, *inter alia*, (1) the invention of U.S. Patent No. 4,535,186 that claims the compound venlafaxine, (2) FDA exclusivities and mandatory 30-month stays of FDA approval of competitor products, and (3) the extensive marketing by Wyeth for the Effexor XR®.

b. Long-Felt Need and Unexpected Results

A prima facie case of obviousness may be rebutted by showing that the claimed invention possesses unexpected results. I*n re Dillon*, 919 F.2d at 692-93. However, a showing of

unexpected results must be based on evidence, and not argument or speculation. *In re Mayne*, 104 F3d 1339, 1343-44 (Fed. Cir. 1997). The results must be unexpected in light of the state of scientific knowledge at the time of the invention. *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997). The '171 patent alleges that it was "completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble." '171 patent at col. 4, lines 57-60. This allegation is incorrect, however, because one of ordinary skill in the art would have expected that substituting venlafaxine for the water-soluble propranolol in the formulations of the '475 patent would have been successful. Indeed, the '171 patent shows that merely substituting venlafaxine for propranolol in the formulations of the '475 patent results in an extended release venlafaxine formulation. There are no other unexpected results disclosed in the '171 patent specification.

B. Double Patenting

At least claims 1, 2, 13, and 14 of the '120 patent are invalid over at least claim 2 of the '171 patent for obviousness-type double patenting. Claims 1, 2, 13, and 14 of the '120 patent are limited to a method of providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period by orally administering an extended release formulation that results in a C_{max} of venlafaxine of no more than about 150 ng/ml. Dependent claims 2, 13, and 14 of the '120 patent add limitations regarding the venlafaxine being in a spheroid and the formulation being encapsulated. Claim 2 of the '171 patent describes an extended release, encapsulated, spheroid formulation of venlafaxine that provides a C_{max} of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period.

There is no patentable distinction between the earlier claim in the '171 patent describing an extended release venlafaxine formulation providing a C_{max} of up to 150 ng/ml and therapeutically effective plasma levels over a twenty four hour period and the later claims to a method of providing therapeutic plasma levels over a twenty four hour period by administering an extended release venlafaxine formulation providing a C_{max} of no more than about 150 ng/ml. The patent specification indicates that the utility of the formulation claimed in the '171 patent is in a method of providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period and providing a C_{max} of 150 ng/ml. '171 patent at col 2, lines 14-18 and col 8, lines 20-27. A person of ordinary skill in the art reviewing the disclosure of the '171 patent

would recognize a single use for the extended release venlafaxine formulation—the use in a method to provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period and to provide a C_{max} of up to 150 ng/ml. Thus, use of the formulation described in the claims of the '171 patent according to its described utility meets every limitation of claims 1, 2, 13, and 14 of the '120 patent. Thus, at least claims 1, 2, 13, and 14 of the '120 patent are invalid for obviousness-type double patenting over at least claim 2 of the '171 patent. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385-86 (Fed. Cir. 2003) ("A claim to a method of using a composition "is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use.").

C. Indefiniteness

In the event that the phrase "extended release formulation" is not construed as discussed above, the claims of the subject patents would be invalid for being indefinite. The claims recite an "extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours." However, these claims fail to provide any information to one skilled in the art regarding, among other things, the features of the formulation or the conditions required to obtain the required times of peak plasma levels set forth in these claims. The claims fail to indicate the nature of the formulation or whether the claimed t_{max} range occurs with the administration of venlafaxine in a fed or fasted state. The claims fail to define a patient condition for which "therapeutic" levels of venlafaxine are intended. The functional limitations of these claims do not distinguish the prior art nor "clearly circumscribe what is foreclosed from future enterprise." Thus, a person of ordinary skill in the art could not determine the bounds of the claims, and the claims are insolubly ambiguous.

In the event that claims 1, 2, 13 and 14 of the '120 patent are not construed as discussed above, these claims would be invalid for being indefinite. Claim 1 recites an extended release formulation of venlafaxine "that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml." Claims 2, 13 and 14 depend from claim 1 and thus also include this limitation. First, the claims do not specify where in the claimed range from 0 to "about 150 ng/ml" the alleged invention of providing a "therapeutic blood plasma of venlafaxine over a 24 hour period with diminished incidence of nausea and emesis" is achieved. Second, these claims fail to provide any information to one skilled in the art regarding, among other things, the

features of the formulation or the conditions required to obtain the required peak plasma levels set forth in these claims. In contrast, the specification repeatedly and uniformly states that the extended release formulations of the invention are comprised of beads or spheres of venlafaxine, microcrystalline cellulose, and hydroxypropylmethylcellulose, which are coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. '171 patent at col 4, lines 9-15. The specification also states that "the desired dissolution rates of sustained release dosage forms of venlafaxine hydrochloride, impossible to achieve with hydrogel tablet technology, has been achieved with the film-coated spheroid compositions of this invention." '171 patent at col 10, lines 53-57. The claims fail to indicate the nature of the formulation or whether the claimed C_{max} range occurs with the administration of venlafaxine in a fed or fasted state. The claims fail to define a patient condition for which "therapeutic" levels of venlafaxine are intended. The functional limitations of these claims do not distinguish the prior art nor "clearly circumscribe what is foreclosed from future enterprise." Thus, a person of ordinary skill in the art could not determine the bounds of the claims, and the claims are insolubly ambiguous. Therefore, claims 1, 2, 13 and 14 of the '120 patent are invalid under § 112, second paragraph.

D. Lack of Enablement

Section 112 requires, *inter alia*, that the patentee provide sufficient information in the written description to teach those in the art to make and use the full scope of the claimed invention. In the event that the claim term "extended release formulation" is construed to mean any extended release formulation regardless of form or excipients, then the claims are not enabled. First, under such a construction, the claims would read upon hydrogel extended release formulations. However, as noted in the '171 specification hydrogel tablets are not enabled by the specification. *See, e.g.*, '171 patent at col 4l lines 57-64. Second, under such a construction, the specification contains no teaching that would enable one of ordinary skill in the art to practice the full scope of the claims without rote trial and error. The '171 specification notes that the formation of spheroids was difficult unless hydroxypropylmethylcellulose 2208 was used or that Hutt and Nica extruders were used. The specification also notes that in order to achieve the claimed blood levels and thus the claimed t_{max} times, the spheroids of venlafaxine, microcrystalline cellulose and hydroxypropylmethylcellulose must be coated at specific levels with ethylcellulose and hydroxypropylmethylcellulose and exhibit a specified dissolution profile.

'171 patent at col 4, lines 9-16; col 6, lines 36-64; and col 10, lines 53-57. Thus, the specification only enables extended release formulations in the form of granules or spheroids of venlafaxine, microcrystalline cellulose and hydroxypropylmethylcellulose that are coated with ethylcellulose and hydroxypropylmethylcellulose. Indeed, Wyeth's own expert asserts that extended release formulation of venlafaxine are so complex and unpredictable that in 1996 the only way to determine if an extended release venlafaxine formulation works is to test it in humans. *See* Supplemental and Rebuttal Expert Report of Ronald J. Sawchuk dated 1/22/2009, *Wyeth v. Apotex*, 1:08-cv-22308-FAM, DI 142, exhibit M. If the claim term "extended release formulation" is construed to mean any extended release formulation regardless of form or excipients, then the specification does not enable one of ordinary skill in the art to practice the full scope of the claims without undue experimentation, such that the claims are invalid for lack of enablement.

III. THE CLAIMS OF THE '171, '120 AND '958 PATENTS ARE UNENFORCEABLE DUE TO INEQUITABLE CONDUCT

The claims of the '171, '120, and '958 patents are unenforceable due to the inequitable conduct of the patentee in withholding material information relevant to the patentability of the claims during prosecution of these patents. In particular, Examiner Spear, the examiner of the '328 application (abandoned), the '629 application (issued at the '171 patent), the '412 application (issued as the '958 patent), and the '965 application (issued as the '120 patent) was not informed of adverse decisions by Examiner Hulina in the priority '137 application (abandoned). During prosecution of the priority '137 application, Examiner Hulina rejected claims 9 and 10 as filed over the '270 patent. The patentee conceded the rejection and agreed to amend the claims in order to obtain their allowance. However, when the patentee subsequently attempted to regain the claim scope they agreed had to be given up in the priority application, the patentee withheld from the new Examiner the information about the adverse decision from Examiner Hulina and their agreement to amend the claims. The information concerning Examiner Hulina's adverse decision and the patentee's claim amendments withheld by the patentee were material, and was withheld by the patentee with an intent to deceive or mislead Examiner Spear in the subsequent applications.

Each of the '171, '120 and '958 patents stem from the same priority application, the '137 application. During prosecution of the '137 application, Examiner Hulina rejected pending claims 9 and 10 for being invalid over U.S. Patent No. 5,506,270. In order to avoid the rejection, the applicant agreed to amend claims 9 and 10 to depend from claim 1. Claim 1 and claims 9 and 10, with the amendments, are shown below.

> 1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropyl methylcellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.
>
> 9. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, [an] the encapsulated, extended release formulation [that] of claim 1 which provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 10. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, [an] the encapsulated, extended release formulation [that] of claim 1 which provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Examiner Hulina allowed the amended claims. However, the applicant did not pay the issue fee and the application went abandoned.

The patentee filed the '328 application as a continuation-in-part, which was assigned to a new examiner, Examiner Spear. The applicant included unamended versions of claims 9 and 10 in the '328 application. However, the applicant failed to inform Examiner Spear about either Examiner Hulina's decision regarding the unpatentability of unamended claims 9 and 10 or the patentee's agreement to narrow the claims in the now-abandoned '137 application to avoid a rejection over the prior art. Similarly, the applicant included unamended claims 9 and 10 in the '629 application, which issued as the '171 patent; and included substantially similar claims in the '412 and '965 applications, which issued as the '958 and '120 patents, respectively. However,

there is no record in the prosecution history of these applications of any disclosure to Examiner Spear concerning Examiner Hulina's rejection of claims 9 and 10 nor of any disclosure of the applicant's agreement to amend claims 9 and 10 to avoid invalidity over the prior art.

Examiner Hulina's rejection of claims 9 and 10 and the applicant's agreement to amend the claims were highly material to the question of the patentability of claims in the '328, '629, '412, and '965 applications. *See*, *e.g.*, *Dayco*, 329 F.3d at 1368. Therefore, there is a strong inference that the patentee intended to deceive Examiner Spear. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1376 (Fed. Cir. 2007). The most reasonable inference to be drawn from this circumstantial evidence is that the patentee intended to deceive the Patent Office. *See*, *e.g.*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008); *see also LaBounty Mfg. v. United States ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("[d]irect proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances.") (citations omitted). Therefore, the claims of the '171, '120, and '958 patents are unenforceable due to the inequitable conduct of the patentee in withholding material information relevant to the patentability of the claims of these patents.

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Appendix A

NONINFRINGEMENT CLAIM CHART – U.S. PATENT NO. 6,274,171

U.S. PATENT NO. 6,274,171	Missing Limitations
1. An extended release formulation of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.	Orchid's proposed product does not contain microcrystalline cellulose, hydroxypropylmethylcellulose, or spheroids.
2. An extended release formulation of venlafaxine hydrochloride according to claim 1 which provides peak serum levels of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period.	See claim 1 and further Orchid's proposed product will not provide peak serum levels of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period
3. An extended release formulation according to claim 1 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP	See claim 1.
4. An extended release formulation according to claim 1 wherein the spheroids are comprised of from about 30% to 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose, NF, by weight, and, optionally, from about 0. 25% to about 1% by weight of hydroxypropylmethylcellulose, USP.	See claim 1.
5. An extended release formulation according to claim 4 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF,	See claim 1.

and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	
6. An extended release formulation according to claim 1 wherein the spheroids comprise from about 6% to about 30% venlafaxine hydrochloride by weight, about 70.1% to about 94% microcrystalline cellulose, NF, by weight and, optionally, from about 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 1.
7. An extended release formulation according to claim 6 wherein the spheroids are coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	See claim 1.
8. An extended release formulation according to claim 1 wherein the spheroids comprise from about 5% to about 25% venlafaxine hydrochloride and from about 95% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 1.
9. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 1.
10. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 20% venlafaxine hydrochloride and from about 94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 1.
11. An encapsulated, extended release formulation of venlafaxine hydrochloride according to claim 1 having the following dissolution profile in USP Apparatus 1 (basket)	See claim 1.

at 100 rpm in purified water at 37° C: [See table in claim].	
12. An extended release formulation according to claim 1 wherein the spheroids are composed of about 37% by weight of venlafaxine hydrochloride, about 0.5% by weight of hydroxypropylmethylcellulose, and about 62% by weight of microcrystalline cellulose.	See claim 1.
13. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (4.81% of total weight) and hydroxypropylmethylcellulose (0.85% of total weight).	See claim 1.
14. An extended release formulation according to claim 1 wherein the film coating comprises 6-8% by weight of total weight.	See claim 1.
15. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (2.48% of total weight) and hydroxypropylmethylcellulose (0.437% of total weight).	See claim 1.
16. An extended release formulation according to claim 1 wherein the film coating composition is comprised of ethyl cellulose having a 44.0-51.0% content of ethoxy groups and hydroxypropylmethylcellulose having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.	See claim 1.
17. An extended release formulation according to claim 1 wherein the film coating composition is comprised of about 85% by total weight of film coating of ethyl cellulose having 44.0-51% content of ethoxy groups and about 15% by total weight of film coating of hydroxypropylmethylcellulose having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.	See claim 1.
18. An extended release formulation according to claim 1 wherein the film coating composition is comprised of 85% by weight of ethyl cellulose having an ethoxy content of	See claim 1.

44.0-51% and a viscosity of 50% cps for a 5% aqueous solution, and 15% by weight of hydroxypropylmethylcellulose having a viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28-30% and a hydroxypropoxy content of 7-12%.	
19. An extended release formulation of venlafaxine hydrochloride for once daily administration which comprises spheroids containing 37.3% venlafaxine, 62.17% microcrystalline cellulose and 0.5% hydroxypropylmethylcellulose coated with a quantity of a mixture comprised of 85% ethyl cellulose and 15% hydroxypropylmethylcellulose sufficient to give coated spheroids having a dissolution profile in USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C.: [see table in claim].	See claim 1.
20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in from about four to about eight hours.
21. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in from about four to about eight hours.
22. A method for providing a therapeutic blood plasma concentration of venlafaxine	Orchid will not practice nor will it induce or contribute to the practice of the claimed

over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in from about five to about eight hours.
23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in about six hours.
24. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in from about five to about eight hours.
25. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in about six hours.

NONINFRINGEMENT CLAIM CHART – U.S. PATENT NO. 6,403,120

U.S. PATENT NO. 6,403,120	Missing Limitations
1. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in from about four to about eight hours nor will it provide peak blood plasma levels of venlafaxine of no more than about 150 ng/ml.
2. The method of claim 1 wherein the extended release formulation is encapsulated.	See claim 1.
3. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose.	See claim 1 and further Orchid's proposed product will not contain spheroids, microcrystalline cellulose or hydroxypropylmethylcellulose.
4. The method of claim 3 wherein the spheroids are comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 3.
5. The method of claim 3 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	See claim 3.
6. The method of claim 5 wherein the spheroids are comprised of about 30% to 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose,	See claim 3.

NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP.	
7. The method of claim 6 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	See claim 3.
8. The method of claim 3 wherein the spheroids are coated with from about 6% to about 30% venlafaxine hydrochloride by weight, about 70.1 % to about 94% microcrystalline cellulose, NF, by weight and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 3.
9. The method of claim 8 wherein the spheroids are coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	See claim 3.
10. The method of claim 3 wherein the spheroids are coated with from about 5% to about 25% venlafaxine hydrochloride and from about 95% to about 75% microcrystalline cellulose, with an optional amount of from 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 3.
11. The method of claim 3 wherein the spheroids are coated with from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	See claim 3.
12. The method of claim 11 wherein the spheroids are comprised of about 6% to about 20% venlafaxine hydrochloride and from about	See claim 3.

94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	
13. The method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid.	See claim 1 and further Orchid's proposed product does not contain spheroids.
14. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid.	See claim 1.

NONINFRINGEMENT CLAIM CHART – U.S. PATENT NO. 6,419,958

U.S. PATENT NO. 6,419,958	Missing Limitations
1. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in from about four to about eight hours.
2. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in from about four to about eight hours.
3. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in from about five to about eight hours.
4. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis nor will it provide a peak blood plasma level of venlafaxine in about six

containing venlafaxine hydrochloride as the active ingredient.	hours.
5. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in from about five to about eight hours.
6. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Orchid will not practice nor will it induce or contribute to the practice of the claimed method. The use of Orchid's proposed product will not provide a peak blood plasma level of venlafaxine in about six hours.

Appendix B

INVALIDITY CLAIM CHART – U.S. PATENT NO. 6,274,171

U.S. PATENT NO. 6,274,171	Prior Art
1. An extended release formulation of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.	Obviousness: Extended release formulations of venlafaxine are disclosed in, *e.g.*, U.S. 5,506,270 at, *e.g.*, 5:23-27; U.S. 5,552,429 at, *e.g.*, 6:36-67 and 8:18-53; and U.S. 5,916,923 at, *e.g.*, 5:44-45. Extended release spheroid formulations are disclosed in, *e.g.*, U.S. 4,138,475 at, *e.g.*, 1:26-49 and 8:40-42; U.S. 4,808,413 at, *e.g.*, 5:15-46; U.S. 4,837,030 at, *e.g.*, 1:7-19; U.S. 5,229,135 at, *e.g.*, 2:27-61; and U.S. 5,273,760 at, *e.g.*, 4:1-28 and 5:59-68. Extended release pellet and granule formulations are disclosed in, *e.g.*, WO 92/01446 at, *e.g.*, 3:25-4:6 and 11:3-22.
2. An extended release formulation of venlafaxine hydrochloride according to claim 1 which provides peak serum levels of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period.	Obviousness: *see, e.g.*, R. Shrivastava et al., J. *Clin. Pharmacol.*, 1994, 14, 322 ("Shrivastava"), the Physicians' Desk Reference, 49th ed. (1995), Goodnick, *Clin. Pharmacokinet.*, 1994, 27, 307 at *e.g.*, 308, 309, 324; and Klamerus et al., *J. Clin. Pharmacol.*, 1992, 32, 716 at, *e.g.*, 722, Table II.
3. An extended release formulation according to claim 1 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP	Obviousness: see claim 1.
4. An extended release formulation according to claim 1 wherein the spheroids are comprised of from about 30% to 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose, NF, by weight, and, optionally, from about 0. 25% to about 1% by weight of hydroxypropylmethylcellulose, USP.	Obviousness: see claim 1.
5. An extended release formulation according to claim 4 wherein the spheroids are	Obviousness: see claim 1.

coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	
6. An extended release formulation according to claim 1 wherein the spheroids comprise from about 6% to about 30% venlafaxine hydrochloride by weight, about 70.1% to about 94% microcrystalline cellulose, NF, by weight and, optionally, from about 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
7. An extended release formulation according to claim 6 wherein the spheroids are coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	Obviousness: see claim 1.
8. An extended release formulation according to claim 1 wherein the spheroids comprise from about 5% to about 25% venlafaxine hydrochloride and from about 95% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
9. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
10. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 20% venlafaxine hydrochloride and from about 94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.

11. An encapsulated, extended release formulation of venlafaxine hydrochloride according to claim 1 having the following dissolution profile in USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C: [See table in claim].	Obviousness: see claim 1.
12. An extended release formulation according to claim 1 wherein the spheroids are composed of about 37% by weight of venlafaxine hydrochloride, about 0.5% by weight of hydroxypropylmethylcellulose, and about 62% by weight of microcrystalline cellulose.	Obviousness: see claim 1.
13. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (4.81% of total weight) and hydroxypropylmethylcellulose (0.85% of total weight).	Obviousness: see claim 1.
14. An extended release formulation according to claim 1 wherein the film coating comprises 6-8% by weight of total weight.	Obviousness: see claim 1.
15. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (2.48% of total weight) and hydroxypropylmethylcellulose (0.437% of total weight).	Obviousness: see claim 1.
16. An extended release formulation according to claim 1 wherein the film coating composition is comprised of ethyl cellulose having a 44.0-51.0% content of ethoxy groups and hydroxypropylmethylcellulose having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.	Obviousness: see claim 1.
17. An extended release formulation according to claim 1 wherein the film coating composition is comprised of about 85% by total weight of film coating of ethyl cellulose having 44.0-51% content of ethoxy groups and about 15% by total weight of film coating of hydroxypropylmethylcellulose having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.	Obviousness: see claim 1.

18. An extended release formulation according to claim 1 wherein the film coating composition is comprised of 85% by weight of ethyl cellulose having an ethoxy content of 44.0-51% and a viscosity of 50% cps for a 5% aqueous solution, and 15% by weight of hydroxypropylmethylcellulose having a viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28-30% and a hydroxypropoxy content of 7-12%.	Obviousness: see claim 1.
19. An extended release formulation of venlafaxine hydrochloride for once daily administration which comprises spheroids containing 37.3% venlafaxine, 62.17% microcrystalline cellulose and 0.5% hydroxypropylmethylcellulose coated with a quantity of a mixture comprised of 85% ethyl cellulose and 15% hydroxypropylmethylcellulose sufficient to give coated spheroids having a dissolution profile in USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C.: [see table in claim].	Obviousness: see claim 1.
20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. *See*, *e.g.*, claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. *See*, *e.g.*, 1:45-60, 3:38-41. A T_{max} of from about 4 to about 8 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. *See*, *e.g.*, Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl

	6A), 6A-24A at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
21. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 4 to about 8 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. See e.g., Wall 12 in Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
22. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of

extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	from about 5 to about 8 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. See e.g., Wall 12 in Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of about 6 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. See e.g., Wall 12 in Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6.

	Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
24. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 5 to about 8 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. See e.g., Wall 12 in Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
25. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood

administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of about 6 hours is inherent in at least the formulations of Examples 1-4. The dosage forms are encapsulated. See e.g., Wall 12 in Fig. 2. Obviousness: *see*, *e.g.*, above claims 1 and 2 and WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6S-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.

INVALIDITY CLAIM CHART – U.S. PATENT NO. 6,403,120

U.S. PATENT NO. 6,403,120	Prior Art
1. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A C_{max} of no more than about 150 ng/ml is inherent in "substantially-avoiding a toxic rang." 3:31-33. Obviousness: Extended release formulations of venlafaxine are disclosed in, *e.g.*, U.S. 5,506,270 at, *e.g.*, 5:23-27; U.S. 5,552,429 at, *e.g.*, 6:36-67 and 8:18-53; and U.S. 5,916,923 at, *e.g.*, 5:44-45. Extended release spheroid formulations are disclosed in, *e.g.*, U.S. 4,138,475 at, *e.g.*, 1:26-49 and 8:40-42; U.S. 4,808,413 at, *e.g.*, 5:15-46; U.S. 4,837,030 at, *e.g.*, 1:7-19; U.S. 5,229,135 at, *e.g.*, 2:27-61; and U.S. 5,273,760 at, *e.g.*, 4:1-28 and 5:59-68. Extended release pellet and granule formulations are disclosed in, *e.g.*, WO 92/01446 at, *e.g.*, 3:25-4:6 and 11:3-22; R. Shrivastava et al., J. *Clin. Pharmacol.*, 1994, 14, 322 ("Shrivastava"), the Physicians' Desk Reference, 49th ed. (1995), Goodnick, *Clin. Pharmacokinet.*, 1994, 27, 307 at *e.g.*, 308, 309, 324; and Klamerus et al., *J. Clin. Pharmacol.*, 1992, 32, 716 at, *e.g.*, 722, Table II.
2. The method of claim 1 wherein the extended release formulation is encapsulated.	Anticipation: encapsulated dosage forms are disclosed in the prior art. See e.g., the '457 patent at Fig. 2 Obviousness: *see* claim 1 and, *e.g.*, the '475 patent at 2:38-44; the '413 patent at 10:32-49; the '030 patent at 7:6-17; the '135 patent at 3:59-65; the '760 patent at 4:1-28; and WO 92/1446 at 4:7-12. .
3. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride,	Anticipation and Obviousness: see claims 1 and 2. Encapsulated (coated) venlafaxine spheroids are disclosed in the '457 patent at 11:63-12:13.

microcrystalline cellulose and optionally, hydroxypropylmethylcellulose.	
4. The method of claim 3 wherein the spheroids are comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
5. The method of claim 3 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	Obviousness: see claim 1.
6. The method of claim 5 wherein the spheroids are comprised of about 30% to 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose, NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP.	Obviousness: see claim 1.
7. The method of claim 6 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	Obviousness: see claim 1.
8. The method of claim 3 wherein the spheroids are coated with from about 6% to about 30% venlafaxine hydrochloride by weight, about 70.1 % to about 94% microcrystalline cellulose, NF, by weight and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
9. The method of claim 8 wherein the spheroids are coated with from about 2% to about 12% of total weight of film coating	Obviousness: see claim 1.

comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.	
10. The method of claim 3 wherein the spheroids are coated with from about 5% to about 25% venlafaxine hydrochloride and from about 95% to about 75% microcrystalline cellulose, with an optional amount of from 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
11. The method of claim 3 wherein the spheroids are coated with from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0. 25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
12. The method of claim 11 wherein the spheroids are comprised of about 6% to about 20% venlafaxine hydrochloride and from about 94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.	Obviousness: see claim 1.
13. The method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid.	Anticipation: Venlafaxine spheroids are disclosed in the '457 patent at 11:63-12:13. Obviousness: see claim 1.
14. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid.	Anticipation: see claims 1-3. Obviousness: see claims 1-3.

INVALIDITY CLAIM CHART – U.S. PATENT NO. 6,419,958

U.S. PATENT NO. 6,419,958	Prior Art
1. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 4 to about 8 hours is inherent in at least the formulations of Examples 1-4. Obviousness: methods of using extended release formulations of venlafaxine are disclosed in, *e.g.*, U.S. 5,506,270 at, *e.g.*, 5:23-27; U.S. 5,552,429 at, *e.g.*, 6:36-67 and 8:18-53; and U.S. 5,916,923 at, *e.g.*, 5:44-45; *see also*, *e.g.*, R. Shrivastava et al., J. *Clin. Pharmacol.*, 1994, 14, 322 ("Shrivastava"), the Physicians' Desk Reference, 49th ed. (1995), Goodnick, *Clin. Pharmacokinet.*, 1994, 27, 307 at *e.g.*, 308, 309, 324; and Klamerus et al., *J. Clin. Pharmacol.*, 1992, 32, 716 at, *e.g.*, 722, Table II. *see also*, *e.g.*, WO 94/27589 at, *e.g.*, 3; Gupta et al., in *Treatise On Controlled Drug Delivery*, Kydonieus ed., Marcel Dekker 1992 at, e.g., 257; Silber et al., "Pharmacokinetic/ Pharmacodynamic Basis of Controlled Drug Delivery," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, 216, Benet et al. in *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 9th Ed, 1996 at, *e.g.*, 6. Andrews et al., *Am. J. Med.*, 1994, 97, (suppl 6A), 6A-24S at, *e.g.*, 6A-30S. The '135 patent at, e.g., 1:13, 2:18-20, 4:55-68; Goodman & Gilman's at, *e.g.*, 1736; Hui et al., "Design and Fabrication of Oral Controlled Release Drug Delivery Systems," in *Controlled Drug Delivery*, 2nd Ed., Robinson & Lee eds., Marcel Dekker, Inc., 1987 at, *e.g.*, p. 375-79, and the '171 patent at, e.g., 1:34-58.
2. A method for eliminating the troughs	Anticipation: The '457 Patent discloses a

and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 4 to about 8 hours is inherent in at least the formulations of Examples 1-4. Obviousness: see claim 1.
3. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 5 to about 8 hours is inherent in at least the formulations of Examples 1-4. Obviousness: see claim 1.
4. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of about 6 hours is inherent in at least the formulations of Examples 1-4. Obviousness: see claim 1.
5. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of from about 5 to about 8 hours is inherent in at least the formulations of Examples 1-4. Obviousness: see claim 1.
6. A method for eliminating the troughs and peaks of drug concentration in a patient's	Anticipation: The '457 Patent discloses a method of providing therapeutic blood plasma

blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.	concentrations of venlafaxine over 24 hours. Claim 1, 3:31-33. The method eliminates troughs and peaks and avoids toxic blood plasma concentrations and ineffective concentrations. 1:45-60, 3:38-41. A T_{max} of about 6 hours is inherent in at least the formulations of Examples 1-4. Obviousness: see claim 1.

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing:

DEFENDANTS' NONINFRINGEMENT AND INVALIDITY CONTENTIONS

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. and ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-03235 (FLW)(DEA) **WYETH'S INITIAL DISCLOSURE STATEMENT PURSUANT TO FED. R. CIV. P. 26(a)(1)**

Plaintiff Wyeth provides this Initial Disclosure Statement in accordance with Fed. R. Civ. P. 26(a)(1). These disclosures are based on information reasonably available to Wyeth as of this date. Wyeth reserves the right to supplement or modify these disclosures.

Thus, Wyeth's disclosures represent a good faith effort to identify discoverable information it currently reasonably believes it may use to support its claims or defenses as required by Fed. R. Civ. P. 26(a)(1). These disclosures do not include information that may be used solely for impeachment purposes.

Wyeth's disclosures are made without waiving, in any way: (1) any claim of privilege or work product; (2) the right to object on the grounds of competency, relevancy and materiality, hearsay, or any other proper ground, to the use of any such information, for any purpose, in

whole or in part, in any subsequent proceeding in this action or any other action; and (3) the right to object on any and all grounds, at any time, to any other discovery request or proceeding involving or relating to the subject matter of these disclosures.

Finally, these disclosures do not identify or otherwise include information concerning experts, as that subject is not covered by Fed. R. Civ. P. 26(a)(1). Wyeth will provide its expert disclosures pursuant to the deadlines set forth in the Federal Rules of Civil Procedure or a Scheduling Order that will be entered by the Court.

All of the disclosures set forth below are made subject to the above objections and qualifications.

I. Rule 26(a)(1)(A) Disclosure

Based on information reasonably available to Wyeth at this time, the following are the names, and if known, the addresses of individuals who are likely to have discoverable information that Wyeth may use to support its claims or defenses, unless used solely for impeachment. The individuals identified may be contacted only through counsel for Wyeth. A brief identification of the subjects on which each listed individual may have such discoverable information is also provided. This list does not include Orgenus Pharma Inc.'s and Orchid Chemicals & Pharmaceuticals Ltd.'s ("Orchid's") employees, agents, or attorneys who are likely to have discoverable information that Wyeth may use to support its claims or defenses as Orchid is fully knowledgeable concerning the identity of and the subject matter known to those individuals.

1. Deborah M. Sherman

   Wyeth
   641 Ridge Road
   Chazy, New York 12921

Subject matter: inventor of United States Patent Nos. 6,274,171 B1; 6,403,120 B1; and 6,419,958 B2 ("the '171, '120, and '958 patents" respectively); subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

2. John C. Clark

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120 and '958 patents; research and development of extended release venlafaxine.

3. John U. Lamer

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

4. Stephen A. White

Wyeth
64 Maple Street
Rouses Point, New York 12979

Subject matter: inventor of the '171, '120, and '958 patents; subject matter of the '171, '120, and '958 patents; assignment and ownership of the '171, '120, and '958 patents; research and development of extended release venlafaxine.

5. Dr. Eliseo Salinas
Adolor Corp.
700 Pennsylvania Drive
Exton, PA 19341

Subject matter: pharmacokinetic and clinical trials and publications relating to Effexor® and/or Effexor XR®; clinical advantages of Effexor XR®; commercial success of Effexor XR®.

6. Jay Bowsher

Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: the significance and importance of the development of Effexor XR®; commercial success of Effexor XR® as compared to Effexor®; drug development and importance of pharmaceutical research and development at Wyeth; ownership of the '171, '120, and '958 patents.

7. Robin P. Enever
18 Pine St
Rouses Point, New York 12979

Subject matter: research and development of extended release venlafaxine.

8. Xin Li
Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: knowledge of Wyeth's electronic database for Wyeth clinical studies involving immediate release venlafaxine and Effexor XR®, and the use of SAS programming to extract treatment emergent study event data from that database.

9. Peter Hunter
Wyeth
500 Arcola Road
Collegeville, PA 19426

Subject matter: IMS Health's data collection and storage, IMS Health products and services, and IMS Health's data on Effexor®, Effexor XR®, and other antidepressant products.

Wyeth expressly reserves the right to identify and call as witnesses additional persons if Wyeth learns during the course of its investigation and discovery in this action that such persons have knowledge of discoverable information that Wyeth may use to support its claims or defenses.

II. Rule 26(a)(1)(B) Disclosure

Based on information reasonably available to Wyeth at this time, Wyeth describes below by category and location the following documents, data compilations, and tangible things in the possession, custody, or control of Wyeth, that Wyeth may use to support its claims or defenses (excluding documents that may be used solely for impeachment):

1. Documents relating to the research, development, and commercialization of extended release venlafaxine HCl capsules as disclosed and claimed in the '171, '120, and '958 patents may be located at Wyeth's facilities in New York, Pennsylvania, and/or New Jersey, and/or at Finnegan Henderson facilities.

2. Documents relating to the preparation, filing, and prosecution of the '171, '120, and '958 patents may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

3. Documents relating to marketing and product sales of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

4. Documents demonstrating the advantages of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

5. Documents relating to the assignment and ownership of the '171, '120, and '958 patents may be located at Wyeth's facilities in Pennsylvania, New Jersey, and/or New York, and/or at Finnegan Henderson facilities.

6. Documents relating to the importance of pharmaceutical research and development at Wyeth may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

7. Documents regarding the commercial success of EFFEXOR XR® may be located at Wyeth's facilities in Pennsylvania and/or New Jersey, and/or at Finnegan Henderson facilities.

8. Documents relating to Orchid's ANDA filings for Venlafaxine HCl Extended-Release capsules are located at Orchid's facilities.

9. Documents relating to Orchid's infringement, the basis for Orchid's paragraph IV certification, its decision to pursue an extended-release venlafaxine product, and other documents relating to the exceptional nature of this case are located at Orchid's facilities.

III. Rule 26(a)(1)(C) Disclosure

Pursuant to Fed. R. Civ. P. 26(a)(1)(C), Wyeth states that under 35 U.S.C. § 271(e)(4)(C), damages or other monetary relief may be awarded in this action only if Orchid violates applicable laws and regulations and engages in the commercial manufacture, use, offering to sell or sale within the United States or importation into the United States of Venlafaxine HCl

Extended-Release capsules. To Wyeth's present knowledge, Orchid has not engaged in such commercial activity to date, and Wyeth therefore makes no claims for damages or other monetary relief in this action at this time. Wyeth reserves the right to assert such claims in the event that Defendants have engaged or do engage in such commercial activity before the expiration date of Wyeth's '171, '120, and '958 patents.

Wyeth seeks an award of its attorney's fees, pursuant to 35 U.S.C. § 285, and costs of suit. The amount of those fees and costs is not yet known.

IV. Rule 26(a)(1)(D) Disclosure

Wyeth is unaware of any apparently pertinent insurance agreements at this time. However, Wyeth reserves the right to supplement this disclosure if any pertinent insurance agreements are identified.

Dated: October 1, 2009

Respectfully submitted

By: Liza M. Walsh

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of **WYETH'S INITIAL DISCLOSURE STATEMENT PURSUANT TO FED. R. CIV. P. 26(a)(1)** was served by electronic mail upon the following counsel for Defendants:

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Dated: October 1, 2009

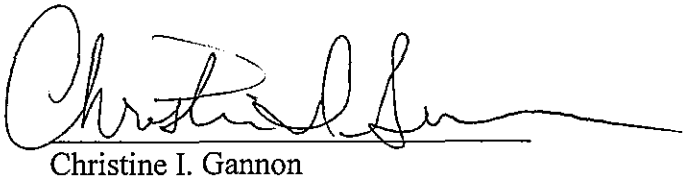

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EXHIBIT 7

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. and ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-03235 (FLW)(DEA) **JOINT DISCOVERY PLAN** Rule 16 Conference November 12, 2009 DOCUMENT FILED ELECTRONICALLY

I. THE PARTIES AND THEIR ATTORNEYS

A. Plaintiff Wyeth

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II. BRIEF DESCRIPTION OF THE CASE, INCLUDING FACTS, CAUSES OF ACTION AND AFFIRMATIVE DEFENSES ASSERTED

This is a civil action for patent infringement under the patent laws of the United States and, in particular, under 35 U.S.C. § 271(e). This action arises from an abbreviated new drug application ("ANDA") filed by Orchid with the United States Food and Drug Administration ("FDA") seeking approval for Orchid to market a generic version of venlafaxine hydrochloride

extended-release capsules before the expiration of Wyeth's patents-in-suit. Venlafaxine hydrochloride extended-release capsules are currently marketed by Wyeth under the brand name Effexor XR®.

In response to Orchid's May 19, 2009 Notice letter providing Orchid's non-infringement and invalidity allegations and after review of Orchid's ANDA provided by Orchid on June 4, 2009, Wyeth filed its Complaint in this action on July 2, 2009. Wyeth seeks, among other things, (1) a judicial declaration that the commercial manufacture, use, offer for sale, sale or importation of Orchid's venlafaxine hydrochloride extended-release capsules would infringe Wyeth's patents-in-suit; (2) an order in accordance with 35 U.S.C. § 271(e)(4)(A) prohibiting FDA approval of Orchid's ANDA until the expiration of the patents-in-suit; and (3) injunctive relief against Orchid under 35 U.S.C. § 271(e)(4)(B).

On September 2, 2009, Orchid filed its Answer to the Complaint, denying infringement and asserting defenses of non-infringement, invalidity, and unenforceability of the patents-in-suit. Orchid denied that Wyeth is entitled to any of the relief requested in its Complaint. Orchid further filed Counterclaims seeking a declaration that its ANDA product does not infringe and would not infringe (either directly or indirectly) any claims of the patents-in-suit and that the claims of the patents-in-suit are invalid and unenforceable.

Wyeth filed its Answer to Defendants' Affirmative Defenses and Counterclaims on September 25, 2009.

III. STATUS OF SETTLEMENT DISCUSSIONS

The parties have communicated regarding settlement, but they have not reached agreement. The parties expect to continue settlement discussions.

IV. THE PARTIES' FED. R. CIV. P. 26(A)(1) DISCLOSURES

The parties exchanged the information required by Fed. R. Civ. P. 26(a)(1) on October 1, 2009.

V. DISCOVERY CONDUCTED TO DATE AND PROBLEMS ENCOUNTERED

A. Discovery Conducted To Date

Orchid produced its entire ANDA 91-123 to counsel for Wyeth on June 4, 2009. Wyeth served interrogatories, requests for production of documents, and requests for admission on Orchid on September 22, 2009. Orchid served written responses on October 26, 2009. Orchid served requests for production of documents on Wyeth on September 21, 2009. Wyeth served written responses on October 26, 2009.

B. Discovery Problems Encountered To Date

Orchid sent Wyeth a letter on October 30, 2009 objecting to its responses to Orchid's Requests For Production and requesting a meet-and-confer to resolve the issues. Wyeth responded to that letter on November 4, 2009. Also on November 4, 2009, Wyeth sent Orchid a letter objecting to Orchid's discovery responses, and requesting a meet-and-confer to resolve those issues. The parties plan to meet and confer on November 5, 2009. No additional discovery problems have been encountered to date.

VI. ANTICIPATED FURTHER DISCOVERY NEEDS

Wyeth's position: The present suit against Orchid is the thirteenth such action Wyeth has brought against companies seeking FDA approval to market generic versions of Wyeth's extended-release venlafaxine hydrochloride product pursuant to an ANDA submitted to the FDA. As in those cases, Wyeth bears the burden of proving patent infringement and is faced with multiple counterclaims challenging its three patents. In previous cases, Wyeth has sought extensive discovery on the defendants' proposed products and their use, including, for example,

information relating to the generic product formulation and development process, the decision to pursue a generic version of Effexor XR®, research and development, the planned promotion and sales of those generic products, and the preparation of the ANDAs for those products.

In those cases where discovery has been taken, Wyeth completed substantially all such fact discovery against the defendant prior to submitting its opening claim construction brief. Wyeth intends to pursue the same extensive discovery from Orchid in this case.

In particular, Wyeth anticipates that fact discovery will be needed concerning infringement of the patents-in-suit, Orchid's ANDA No. 91-123 and the products that are the subject of that ANDA, including all design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA No. 91-123 and the products that are the subject of the ANDA; any information Orchid has regarding Effexor XR® and the patents-in-suit, including but not limited to use by Orchid of the patents-in-suit and/or Effexor XR® in developing the products that are the subject of ANDA No. 91-123, the commercial success of Effexor XR® and the side-effects associated with immediate-release venlafaxine, and Orchid's basis for submitting its ANDA to the FDA with a Paragraph IV certification and for bringing affirmative defenses and counterclaims asserting that the patents-in-suit are invalid, unenforceable, or not infringed by Orchid's extended-release venlafaxine products. This discovery is relevant to rebutting Orchid's invalidity allegations. Regarding claim construction, in particular, Wyeth anticipates that fact discovery will be needed concerning the understanding of Orchid personnel of various disputed claim terms, such as "extended release formulation" and "diminished incidences of nausea and emesis." Wyeth further anticipates the need for fact discovery regarding the use by Orchid of Wyeth's patents in developing Orchid's generic version of Effexor XR®. Such fact discovery is relevant to the claim construction issues

in this case, *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Wyeth also anticipates the need to take the depositions of any experts Orchid may rely upon to support its claim construction positions. Indeed, the local patent rules expressly recognize the need for such discovery and the exchange of other information prior to *Markman* briefing. *See* Patent rule 4.4. The fact that Wyeth has asserted the patents-in-suit in prior cases against other generic drug manufacturers with different drug formulations and different claim construction theories does not justify dispensing with the procedures for claim construction established under this Court's patent rules.

Wyeth, moreover, anticipates that it will produce over one million pages of documents, including the pleadings, expert reports, and Wyeth's discovery responses from the related cases. While the availability of this extensive prior discovery should reduce Orchid's need for discovery from Wyeth in this case, defendants in the related cases that likewise received prior discovery and pleadings nonetheless have aggressively pursued additional discovery, including seeking to re-depose fact witnesses who have given multiple depositions in the prior related cases. Defendants in the prior cases have also insisted on conducting their own depositions of Wyeth under Rule 30(b)(6), despite access to Wyeth's comprehensive Rule 30(b)(6) testimony from prior related cases and despite initially insisting in several cases that extensive discovery from Wyeth would be unnecessary.[1]

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[1] In the *Wyeth v. Teva* litigation, the parties took a total of 37 depositions consisting of 11 expert depositions, 5 Rule 30(b)(6) depositions, and 21 fact depositions. The depositions spanned a period of 13 months. In the *Wyeth v. Impax* litigation, the parties took a total of 29 depositions consisting of 10 expert depositions, 9 Rule 30(b)(6) depositions, and 10 fact depositions. The depositions spanned a period of over 10.5 months. In the *Wyeth v. Anchen* litigation, the parties took a total of 24 depositions consisting of 13 expert depositions, 1 Rule 30(b)(6) deposition, and 10 fact depositions. The depositions spanned a period of 13 months. In the *Wyeth v. Lupin* litigation, the parties took a total of 30 depositions consisting of 14 expert depositions, 2 Rule 30(b)(6) deposition, and 14 fact depositions. The depositions spanned a period of 7 months. In the *Wyeth v. Mylan* litigation, the parties took a total of 19 depositions consisting of 9 expert depositions, 2 Rule 30(b)(6) deposition, and 8 fact depositions. The depositions spanned a period of 8 months. In the *Wyeth v. Sandoz*, litigation, the parties took a total of 9 depositions consisting of 4 expert

(continued on next page)

Furthermore, expert disclosures are a necessary element in a technologically complex case such as this. Wyeth contemplates providing expert testimony on at least the areas of psychiatry, pharmacokinetics, pharmacodynamics, pharmaceutical formulations, biostatistics, and economics. Wyeth further anticipates that Orchid will designate opposing experts and that extensive expert depositions will be conducted.

Accordingly, as set forth in Section VII below, Wyeth proposes approximately 8 months from now for fact discovery and approximately 7 weeks for expert discovery in this case, which is comparable to the discovery periods in the prior related cases, as the following chart shows:

(continued from previous page)
depositions, 2 Rule 30(b)(6) depositions, and 3 fact depositions. The depositions spanned a period of 12 months. In the *Wyeth v. Apotex* litigation, the parties took a total of 33 depositions consisting of 14 expert depositions, 3 Rule 30(b)(6) depositions, and 16 fact depositions. The depositions spanned a period of 5 months.

Table A

DEFENDANT	CASE NO. (COURT)	COMPLAINT FILED	FACT DISCOVERY DEADLINE	MARKMAN HEARING — ORDER ISSUED	TRIAL DATE
Teva	CV 03-1293 (NJ)	3/24/2003	9/2/2004	8/29/2005 — 9/6/2005	10/11/2005 (Settled on eve of trial)
Impax	CV 06-222 (DE)	4/5/2006	None	6/12/2007 — 12/13/2007	4/9/2008 (Settled on eve of trial)
Anchen	CV 06-386 JVS (CD Cal)	4/12/2006	11/16/2007	11/9/2007 — 12/21/07	9/9/2008 (Settled)
Lupin	07-CV - 00632 (MD)	3/12/2007	5/20/2008	Not Conducted	3/23/2009 (Settled)
Osmotica	7:07-CV-67-D (EDNC)	4/20/2007	3/31/2008	1/22/2008	N/A (Settled on eve of *Markman* Hearing)
Sandoz	07-CV-00234 (EDNC)	6/22/2007	10/29/2008	5/29/2008 — 7/3/2008	TBD
Mylan	07-CV-91 (NDWV)	7/6/2007	3/31/2009	3/2/2009 — 5/22/2009	10/13/2009 (Settled on eve of trial)
Wockhardt	CV 07-5166 JVS (CD Cal)	8/8/2007	N/A	N/A	(Settled)
Biovail	TBD (DE)	6/26/2008	N/A	N/A	TBD

DEFENDANT	CASE NO. (COURT)	COMPLAINT FILED	FACT DISCOVERY DEADLINE	MARKMAN HEARING — ORDER ISSUED	TRIAL DATE
Apotex	08-22308-CIV-MORENO	8/18/2008	3/6/09	Claim Construction rendered in Magistrate Judge Torres' Summary Judgment Report Rendered on August 15, 2009, Pending Review by U.S. District Judge Moreno	1/19/2010
Torrent	09-019 (JJF)	1/8/2009	TBD	TBD	TBD (Stayed)
Zydus	09-239 (JJF)	4/9/2009	TBD	TBD	TBD

Orchid's position: Rather than adopting an artificially prolonged schedule at the outset, the better approach under the circumstances is to provide the parties with an expedited schedule for the completion of discovery. Orchid believes that, because Wyeth has already litigated in twelve prior cases the same issues that are at issue here, this case can and should be expedited and placed on a faster track than if this were the first case that Wyeth had instituted concerning generic extended-release venlafaxine. In light of the existence of the records from the twelve similar cases that Wyeth has brought, Orchid believes that it will need to conduct only targeted supplemental discovery. Orchid promptly served document requests on Wyeth seeking production of, among other things, all filings, court transcripts, and expert reports from those twelve earlier cases. Wyeth has not yet produced any documents in response to that request. Hence, at this time, Orchid cannot yet make informed judgments about what additional discovery

it will need to conduct. However, based on the extensive records developed in the twelve prior cases, Orchid fully expects that it will need to take only limited additional discovery in this case.

Orchid believes that Wyeth overestimates the amount of discovery required both before Markman briefing and for the case as a whole. Orchid expects that Wyeth will proffer the same claim construction positions in this case as it did in the previous twelve cases. Orchid does not believe that Wyeth needs any additional fact discovery from Orchid concerning claim construction of Wyeth's own patents for Markman briefing. The "design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA" that were conducted in 2008 cannot have any bearing on the construction of claims in a patent filed over a decade earlier, in 1996. With respect to its burden of proving infringement, Wyeth has to establish (as in the previous cases) that "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). "Of course, this hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support." Id. Again, the "design, research, development, testing, planning, projections (including but not limited to sales and profit projections), and communications relating to ANDA" have little, if any, bearing on the issue of infringement. In any event, Orchid expects to promptly provide Wyeth with the "extensive discovery from Orchid" described above.

VII. THE PARTIES' MEETING PURSUANT TO FED. R. CIV. P. 26(f)

The parties first met and conferred pursuant to Fed. R. Civ. P. 26(f) by telephone on September 17, 2009, and have continued their discussion since that time.

The parties have worked together to try to reach agreement on the dates and other topics that are the subject of this plan.

To the extent the parties were unable to agree on a particular issue, the parties' competing proposals are presented.

	Local Patent Rule (where applicable)	Wyeth's Proposed Schedule	Orchid's Proposed Schedule
Initial Scheduling Conference		11/12/2009	11/12/2009
Defendant invalidity and noninfringement contentions due	3.6(b), (d) (14 days)	11/26/2009 (14 days)	11/19/2009 (7 days)
Plaintiffs asserted claims and infringement contentions due	3.6(f) (45 days)	1/8/2010 (45 days)	12/3/2009 (14 days)
Exchange claim terms	4.1 (14 days)	1/22/2010 (14 days)	12/10/2009 (7 days)
Exchange proposed constructions	4.2 (21 days)	2/12/2010 (21 days)	12/17/2009 (7 days)
Deadline for joining other parties and amending the pleadings		2/26/2010	2/26/2010
Joint claim construction statement	4.3 (30 days)	3/12/2010 (28 days)	1/8/2010 (22 days)
Complete claim construction discovery	4.4 (30 days)	4/9/2010 (28 days)	2/15/2010 (38 days)
Opening *Markman* Briefs	4.5 (45 days)	4/23/2010 (42 days)	3/5/2010 (18 days)
Responding *Markman* Briefs	4.5 (60 days)	6/22/2010 (60 days)	4/2/2010 (28 days)
Confer re claim construction hearing schedule	4.6 (2 weeks)	7/6/2010[2] (2 weeks)	4/9/2010 [3] (7 days)

[2]Wyeth submits that live testimony is not required for the claim construction hearing, and that four hours should be sufficient for the hearing. Wyeth does not believe that a separate tutorial is necessary.

[3] Orchid proposes that the court decide the length of the hearing, whether to have live testimony and whether a separate tutorial is needed.

	Local Patent Rule (where applicable)	Wyeth's Proposed Schedule	Orchid's Proposed Schedule
Close of Fact Discovery		7/30/2010	5/21/2010
Opening Expert Reports		11/22/2010[4]	6/18/2010
Responsive Expert Reports		1/15/2011	7/16/2010
Close of Expert Discovery		2/28/2011	9/03/2010
Filing opening briefs in support of dispositive motions		3/31/2011	9/17/2010
Proposed Trial Date		7/18/2011	1/10/2011

Wyeth's Comments Regarding Orchid's Proposal

Wyeth has already explained the bases and rationale for its proposed schedule, which Wyeth submits is entirely consistent with the timeframes set forth in the local patent rules. (See Section VI, above). Wyeth submits Orchid's proposal, which significantly truncates many of the patent rules' deadlines, is unworkable because, among other things, it does not provide enough time for discovery before *Markman* briefing, does not provide enough time for discovery in general, and key dates in the schedule conflict with the schedule in *Wyeth v. Apotex*, where trial begins on January 19, 2010, and will be preceded by extensive pretrial preparation involving the same attorneys, fact witnesses, and experts who will be involved in discovery and *Markman* proceedings in this case.

Furthermore, Orchid's proposed schedule is inconsistent with the schedules in the prior related cases, as shown above. In particular, Orchid's schedule is at odds with the schedules

[4] Wyeth proposes this date to allow sufficient time for a Markman hearing and for the Court to issue a claim construction order. Wyeth submits that requiring expert reports before the Court's Markman order would be inefficient and would impose unnecessary burdens and expense on the parties.

adopted by the two other courts that, like New Jersey, have adopted patent rules. In *Wyeth v. Anchen*, (C.D. Cal.) the court set the discovery to close 19 months from the date of the complaint, while in *Wyeth v. Sandoz*, (E.D.N.C.) discovery ended 16 months from the date of the complaint. Orchid's proposed schedule, in contrast, would compress all discovery into just 14 months from the date of the complaint.

It is particularly unrealistic to propose, as Orchid does, that all claim construction discovery be completed by February 15, 2010, just three months from now. The parties have not yet produced documents in response to each other's document requests. What is more, experience has shown the futility of compressed schedules such as Orchid proposes. In *Wyeth v. Apotex*, for example, the court initially issued accelerated schedule and declined to modify it after Apotex insisted that it needed only minimal discovery. Ultimately, that expedited schedule could not be met, and the Court granted Wyeth's renewed motion to push back all dates. Instead of a trial in February 2009, trial was rescheduled for June 2009. Even then, the modified schedule proved inadequate, leaving the court insufficient time to address dispositive motions and in limine motions. The court *sua sponte* pushed back the trial date by another four months. Similar problems occurred in *Wyeth v. Lupin,* where the Court initially adopted an accelerated schedule after Lupin represented that it required only minimal deposition discovery from Wyeth. Lupin then sought to depose numerous Wyeth fact witnesses, necessitating an extension of the discovery period and other dates. Orchid's suggestion that Wyeth should prepare its *Markman* briefs by "rote" ignores the fact that this case, like each of the preceding cases, is unique. Orchid has yet to set forth claim construction positions, and therefore, it is entirely premature to conclude that "shortcuts" to conducting claim construction proceedings and fact discovery should be implemented here. Orchid suggests that accelerating *Markman* proceedings may

facilitate settlement. (*See* p. 16). But there is no assurance that a *Markman* ruling will result in a prompt settlement. In Wyeth *v. Sandoz*, for example, the court issued its *Markman* ruling on July 3, 2008. That case remains pending.

In short, Orchid's proposed schedule departs significantly from the orderly progression of events contemplated by the local patent rules. It also departs significantly from the schedules adopted by the other courts in related prior Effexor XR litigations. Those schedules, like the one proposed here, are consistent with the timetable for litigations envisioned by Congress under the Hatch-Waxman Act. The Act provides for a 30-month stay of approval for Orchid's ANDA while this case is being litigated. Wyeth's proposed trial date of July 18, 2011 is three months prior to the expiration of the 30-month stay in this case, and thus provides for resolution of this case in an appropriate timeframe as contemplated by the Hatch-Waxman Act. Orchid suggests that an expedited trial in this case would provide an opportunity to launch its generic product after Teva's exclusivity expires at the end of 2010. (*See* p. 16). Orchid, however, does not factor in an appeal to the Federal Circuit by Wyeth in the event of a judgment in Orchid's favor. If Orchid were to launch its product before appellate review by the Federal Circuit, that launch would be "at risk" and would expose Orchid to the prospect of substantial monetary damage if the Federal Circuit were to reverse a district court judgment in Orchid's favor. Because of that huge financial exposure, generic drug manufacturers rarely undertake such "at risk" launches. Furthermore, even with a trial in January, 2010, as Orchid proposes, the Federal Circuit would likely not decide an appeal from the district court's judgment until after June, 2011. Finally, Orchid does not state that the FDA has finished reviewing its ANDA and has tentatively approved Orchid's generic product. Without such tentative approval, Orchid cannot launch its product regardless of the outcome of this case.

Orchid's Comments Regarding The Proposed Schedules

As noted above in Orchid's comments, Orchid submits that this is not a typical patent case requiring a typical patent discovery schedule. Claim construction has been briefed at least seven times previously, including once in this Court before Judge Martini. There is no legitimate reason why Wyeth cannot meet Orchid's proposed Markman schedule. Wyeth has had Orchid's non-infringement and invalidity contentions and a copy of its entire ANDA 91-123 for over five months. That is more than ample time for Wyeth to formulate and provide its infringement contentions. Even assuming the relevance of Wyeth's counsel's schedules in other cases that Wyeth has chosen to bring, the only activity required of Wyeth's counsel in this case prior to its scheduled trial date with Apotex involves the recitation of its previous claim construction positions. The proposed schedule also provides a reasonable time after the Apotex trial will be completed before opening Markman briefs are due. Further, according to Wyeth's Table A, there is a substantial possibility that the Apotex case will settle—given that most of the cases settled shortly after the Markman order issued. In any event, Wyeth's opening Markman brief would again merely require only rote recitation of its previous Markman positions.

Wyeth points out that discovery in Wyeth v. Sandoz was completed 16 months after the complaint was filed. Orchid proposes that discovery in this case be completed 14 months after the complaint was filed. As Wyeth notes above, "the availability of this extensive prior discovery should reduce Orchid's need for discovery from Wyeth in this case." Indeed, Orchid reasonably believes that much of the discovery accomplished in the prior cases will not have to be repeated in this case.

This patent case is governed by the Hatch-Waxman statutes. Under this statutory scheme, Orchid's ANDA 91-123 is subject to a 30-month stay of approval whereby FDA is

prevented from granting marketing approval for Orchid's ANDA until the earlier of November 21, 2011 or the date a district court decides the asserted patents are invalid or not infringed by Orchid's ANDA product. Pursuant to the settlement with Teva, Wyeth has permitted Teva to launch its generic product on July 1, 2010. Under the Hatch-Waxman statutory scheme, Teva (along with Wyeth) will have marketing exclusivity until December 28, 2010, after which time FDA will be permitted to approve all other ANDAs not otherwise subjected to a 30-month stay. Orchid's proposed schedule would permit Orchid the potential opportunity to launch its ANDA product shortly after the FDA would be permitted to approve all ANDAs if this Court renders a decision in its favor. In contrast, Wyeth's proposed schedule pushes the potential approval date of Orchid's ANDA almost to the expiration of the 30-month stay, after which Orchid's ANDA could be approved absent a finding of invalidity or non-infringement. Wyeth's proposed schedule conflicts with the Hatch-Waxman statutory scheme, which requires that each of the parties shall "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

Orchid's proposed schedule encourages a quick Markman order. In the prior venlafaxine cases the Markman order was soon followed by settlement. Under any of the previous Markman orders, Orchid is confident it will prevail on either non-infringement or invalidity at trial.

There is much upside to adopting Orchid's proposed schedule. If Orchid is correct that the documents that is has already requested from Wyeth contain the vast majority of the discovery that would ordinarily be taken in a "first" case on a patent, then the schedule it proposes will be more than adequate for the parties, and this case can be expeditiously resolved. Orchid's schedule is wholly consistent with the objectives of the Hatch-Waxman statutory scheme, and has the greatest likelihood of resolving this case promptly. Conversely, there is no downside to adopting Orchid's proposed schedule. If it turns out that, for whatever reason, the

schedule will need to be adjusted in the future, then that can easily happen either by agreement of the parties or by ruling of the Court. Adopting Wyeth's proposed schedule at the outset on the assumption that this case will proceed as slowly as a "first" case serves no purpose, would slow the disposition of this case, and is contrary to the public policy underpinnings of the Hatch Waxman Act.

VIII. OTHER DISCOVERY MATTERS

A. Interrogatories

The parties do not seek any change to the limitations imposed under the Federal or Local rules.

B. Depositions

The parties agree that each side shall be permitted to take 10 fact depositions and further agree that the limitation of 10 depositions per side is inapplicable to expert depositions.

Orchid requests that the Court permit the deposition(s) of Orchid fact witness(es) who are located in India to take place by video conference.

Wyeth requests that the Court require that Orchid fact witnesses who are located in India be required to present themselves for deposition within this judicial district or at a place agreed to by the parties. To date, Orchid has identified just one individual in its Rule 26(a) declaration and in responses to interrogatories as having knowledge of the subject matters at issue in this case. Requiring Wyeth to depose that individual, and others in India who undoubtedly possess discoverable information by video conference, will unnecessarily hamper discovery and will disadvantage Wyeth. Deposition by video conference simply is not a viable alternative to a traditional deposition. Since Orchid has asserted multiple counterclaims in this case, it should be required to present witnesses residing in India for deposition in this judicial district.

C. Special discovery mechanisms or procedures

1. Electronic Discovery

Documents will be produced in single-page TIFF images except for minor exceptions, such as for clinical data.

2. Other Discovery Needs

The parties do not now anticipate any special discovery needs.

3. Protective Order

This action will require the disclosure of confidential or proprietary technical and financial information. The parties have submitted a stipulated discovery confidentiality order. The order includes provisions relating to materials protected under the attorney-client privilege or work product immunity, including procedures for dealing with the inadvertent production of such materials.

IX. EXPERT TESTIMONY

As reflected by the proposed schedule, the parties anticipate retaining expert witnesses. The proposed schedule set forth in Section VII offers the parties' respective proposed deadlines for the production of expert reports and for expert depositions.

X. ALTERNATIVE DISPUTE RESOLUTION

Wyeth submits that this case is not one that might be resolved by alternative dispute resolution. Such proceedings in prior related cases have not been fruitful.

Orchid submits that this case may potentially benefit from a settlement conference with the Magistrate Judge in early 2010.

Respectfully submitted,

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EXHIBIT 8

Not Reported in F.Supp.2d, 2006 WL 3826726 (N.D.Cal.)
(Cite as: 2006 WL 3826726 (N.D.Cal.))

United States District Court,
N.D. California.
SEMICONDUCTOR ENERGY LABORATORY COMPANY LTD, Plaintiff,
v.
CHI MEI OPTOELECTRONICS CORP., et al., Defendant(s).
No. C 04-04675 MHP.

Dec. 27, 2006.

David Eiseman, Quinn Emanuel Urquhart Oliver & Hedges, LLP, Redwood City, CA, Donald R. Harris, Joseph Albert Saltiel, Stanley A. Schlitter, Stephen M. Geissler, Terrence Joseph Truax, Jenner & Block LLC, Chicago, IL, Victoria F. Maroulis, R. Tulloss Delk, Quinn Emanuel Urquhart Oliver & Hedges, LLP, Redwood Shores, CA for Plaintiff.

Scott R. Mosko, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Palo Alto, CA, for Defendants.

MEMORANDUM & ORDER

Re: Defendants' Motions to Amend Answers and Counterclaims; Plaintiff's Motion to Strike Expert Report

MARILYN HALL PATEL, United States District Judge.

***1** Defendants Chi Mei Optoelectronics Corp. ("CMO"), International Display Technology Co., Ltd., International Display Technology USA, Inc., and Westinghouse Digital Electronics, LLC (collectively "defendants") have filed four substantively identical motions to amend their answers and counterclaims. Defendants seek to add the affirmative defenses of license, equitable estoppel, and patent invalidity due to inequitable conduct, to plead additional facts related to their previously pled defenses of laches and patent misuse, and to delete previously pled affirmative defenses related to claims that have since been dismissed. Plaintiff Semiconductor Energy Laboratory Co. Ltd. ("plaintiff") opposes the motions. Relatedly, plaintiff moves to strike the expert report of Gerald Mossinghoff, which defendants have submitted in support of their inequitable conduct claims. Having considered the parties' arguments and for the reasons stated below, the court enters the following memorandum and order.

BACKGROUND

Plaintiff filed this action on November 3, 2004, asserting claims for patent infringement. Defendants filed their original answers and counterclaims on February 28, 2005. On August 11, 2006, the parties filed a stipulation that all claims and defenses related to one of the asserted patents be dismissed with prejudice. This is the first time defendants have sought to amend their answers and counterclaims.

The fact discovery cutoff was September 15, 2006, and expert discovery cutoff was December 18, 2005. However, the parties agreed to take-and did take-additional factual depositions in September and October 2006. Defendants deposed Eric J. Robinson, plaintiff's patent attorney, on September 8, 2006. Defendants deposed Norihiko Seo, Nobuaki Kimura, and Akira Takenouchi, plaintiff's licensing representatives, during the last week of September 2006. Defendants also deposed Shumpei Yamazaki, plaintiffs' president and the named inventor on two of the patents in suit, on August 24-27, 2006, near the close of fact discovery. In addition, complete documentary evidence related to plaintiff's licensing agreements was not produced until mid-September 2006, after the parties resolved a discovery dispute related to the scope of the production. As of the date of this motion no expert depositions have been taken.

Defendants claim that the depositions taken in August and September 2006, together with the non-redacted license agreements produced in September 2006, revealed previously unknown facts that lend further support to certain of defendants' existing defenses and support additional affirmative defenses that have not been pled. Specifically, defendants assert that the testimony of Yamazaki and Roberts revealed, for the first time, that Yamazaki and Roberts

knew of certain prior art references and information related to the field of the invention that were improperly withheld from the U.S. Patent Office. In addition, defendants assert that the newly discovered identities of plaintiff's licensees (which remain confidential), combined with recent testimony from plaintiff's licensing representatives, support a new allegation that defendants are not liable based on existing licenses. Defendants further assert that the testimony of the licensing agents, together with plaintiff's damages expert report dated October 16, 2006, reveals that plaintiff is seeking improper licensing arrangements and demanding improper royalties, giving rise to a proposed new defense of patent misuse. Finally, defendants claim that the licensing representatives' testimony lends additional factual support to the defenses of equitable estoppel and laches.

***2** During a September 27, 2006 face-to-face conference regarding defendants' affirmative defenses, plaintiff's counsel requested that defendants provide additional discovery responses regarding patent misuse and laches, but stated that the forthcoming report of Gerald Mossinghoff, one of defendants' experts, would be sufficient to satisfy this request. Unikel Dec. ¶ 3. Plaintiff asserts that this was the first time defendants identified Mossinghoff as an expert or raised the issue of an expert report regarding inequitable conduct. On October 6, plaintiff's counsel confirmed its position by letter, coupled with an explicit reservation of rights regarding all of defendants' affirmative defenses and counterclaims. *Id.* ¶ 4. Defendants served their supplemental discovery responses on October 13, 2006 related to equitable estoppel, laches and patent misuse. Mikulka Dec., Exh. 11. Defendants had also made it clear that they were pursuing an inequitable conduct defense at least as early as June 20, 2006, when they served and filed a letter brief regarding discovery disputes that specifically identified defendants' inequitable conduct defense as a grounds for the relevance of one of its outstanding interrogatories. *Id.*, Exh. 15. Mossinghoff's report was issued on October 16, 2006.

As detailed in its Motion to Strike Mossinghoff's expert report, plaintiff claims that defendants intentionally concealed their inequitable conduct defense for more than eighteen months, asserting it only after the close of discovery. In its initial response to plaintiff's first set of interrogatories, CMO stated that the patents were unenforceable because they were invalid, and that CMO would supplement the response when discovery was complete. Schlitter Dec., Exh. 3. As defendants acknowledge, defendants never provided specific information regarding inequitable conduct via discovery responses, due in part to an alleged understanding between the parties that such information would be provided via Mossinghoff's report. Plaintiff also cites correspondence by plaintiff's counsel dated May 17, 2005 purporting to confirm defense counsel's representation that they were not pursuing an inequitable conduct claim. Schlitter Dec., Exh. 5. In addition to this allegedly dilatory conduct on the part of defendants, plaintiff asserts that the information supporting defendants' proposed inequitable conduct claim were known to them early in the litigation, and therefore this late amendment is inappropriate. Plaintiff likewise faults defendants for failing to disclose information related to their other defenses until after the close of fact discovery.

LEGAL STANDARD

The Federal Rules of Civil Procedure provide that leave to amend be "freely given when justice so requires." Fed. R. Civ. Pro. 15(a). The Ninth Circuit has construed this broadly, requiring that leave to amend be granted with "extraordinary liberality." *Morongo Band of Mission Indians v.* Rose, 893 F.2d 1074, 1079 (9th Cir.1990); *see also DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir.1987) (Rule 15's policy of favoring amendments to pleadings should be applied with "extreme liberality"); *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 989 F.Supp. 1237, 1241 (N.D.Cal.1997) (Jensen, J.) ("[T]he court must be very liberal in granting leave to amend"); *Poling v. Morgan*, 829 F.2d 882, 886 (9th Cir.1987) (describing a "strong policy permitting amendment").

***3** Despite this liberal policy of amendment, courts must consider "four factors relevant to whether a motion for leave to amend pleadings should be denied: undue delay, bad faith or dilatory motive, futility of amendment, and prejudice to the opposing party." *United States v. Webb*, 655 F.2d 977, 980 (9th Cir.1981); *see also Poling*, 829 F.2d at 886. The enumerated factors are not of equal weight and delay alone is insufficient to deny leave to amend. *Id.* (citing *Howey v. United States*, 481 F.2d 1187 (9th Cir.1973)). By the same token, "[p]rejudice to the opposing party is the most important factor."

Jackson v. Bank of Hawaii, 902 F.2d 1385, 1387 (9th Cir.1990). The party opposing leave to amend bears the burden of showing prejudice. *DCD Programs*, 833 F.2d at 187.

DISCUSSION

I. *Motion for Leave to Amend*

The four factors relevant to whether defendants' motions should be denied are "undue delay, bad faith or dilatory motive, futility of amendment, and prejudice to the opposing party." *Webb*, 655 F.2d at 980. (9th Cir.1981); *see also Poling*,*829* F.2d at 886. Delay alone is insufficient to deny leave to amend. *Id.* "Prejudice to the opposing party is the most important factor." *Jackson*, 902 F.2d at 1387. The party opposing leave to amend bears the burden of showing prejudice. *DCD Programs*, 833 F.2d at 187.

A. *Undue Delay*

"Relevant to evaluating the delay issue is whether the moving party knew or should have known the facts and theories raised by the amendment in the original pleading." *Jackson*, 829 F.2d at 1388. Plaintiff asserts that defendants have unduly delayed in seeking to amend because (1) all of the information supporting the inequitable conduct defense has been known to defendants for over a year and a half, (2) the facts underlying the equitable estoppel, laches and license defenses should have been known to CMO in 2001 when it was copied on correspondence it seeks to submit as evidence, and (3) defendants should have been aware of the facts underlying their patent misuse defense based on the licenses they received in discovery in 2005. Plaintiff further asserts that the delay is exacerbated by defendants' "repeated failure to cure deficiencies by previous amendments," claiming that defendants had ample opportunity to amend their answers and counterclaims throughout the litigation. Finally, plaintiff faults defendants for waiting several additional weeks after Mossinghoff's report was issued on October 16, 2006 before filing this motion.

Plaintiff's argument is unconvincing. While the documentary evidence may have been previously known to defendants, the full significance of these documents was not apparent until after defendants were able to obtain testimony regarding the documents in Fall 2006. Only then were defendants able to sufficiently formulate their additional defenses for inclusion in amended answers and counterclaims. For this reason, too, defendants did not waste previous opportunities to make amendments. With respect to inequitable conduct in particular, defendants would not have been able to plead inequitable conduct with sufficient specificity prior to obtaining witness testimony and without falling afoul of Federal Rule of Civil Procedure 11. See *Optical Coating Lab., Inc. V. Applied Vision, Ltd.*, No. C-92-4689 MHP, 1995 WL 150513, at *4 (N.D.Cal. Mar. 20, 1995) (Patel, J.) (holding that pursuing an inequitable conduct claim without a specific factual basis raised the specter of Rule 11 sanctions for having pled the claim). The court likewise does not find the delay of less than a month between Mossinghoff's report (October 16) and defendants' motion to amend (November 14) to be unduly long. Accordingly, there is no undue delay.

B. *Bad Faith or Dilatory Motive*

***4** Plaintiffs claim that defendants have a dilatory motive based on defendants' failure to amend earlier, their failure to respond to discovery requests regarding inequitable conduct, and their inclusion of twenty-three additional prior art references in their proposed amended answers and counterclaims. The record indicates, however, that defendants did not provide specific responses to discovery requests concerning inequitable conduct because they were in the process of developing a factual basis for their purported claim. As discussed above, defendants could not have provided any specificity prior to questioning the inventor and plaintiff's patent counsel regarding their conduct related to prosecution. The court therefore does not find that defendants have acted with bad faith or a dilatory motive.

C. *Futility of Amendment*

Plaintiff does not explicitly raise an argument that allowing defendants to amend their answers and counterclaims would be futile. The court considers this factor to be of significant importance, and plaintiff's counsel's response to the court's questions on this factor were no more helpful than their pleadings. Plaintiff does suggest that defendants' proffered evidence does not support their proposed defenses. While the court may question some of defendants' inferences, these factual disputes need not be re-

solved at this stage. The court finds that any factual defects in defendants' evidence do not render their proposed defenses futile, and as plaintiff failed to specifically argue this point this factor weighs heavily in favor of allowing amendment.

D. *Prejudice*

Plaintiff asserts prejudice on two grounds. First, plaintiffs claim that allowing defendants to proceed with their inequitable conduct claim would add a total of 31 new prior art references (eight through Mossinghoff's report and 23 through the amended answers and counterclaims), and that analyzing these references in the seven months before trial would be a "gargantuan task." In addition, plaintiff asserts that it will not be able to engage in sufficient discovery regarding defendants' new defenses because fact discovery has closed. In particular, plaintiff claims that additional discovery would be required to determine whether defendants' products were covered by the licenses at issue, and to explore defendants' purported reliance in the context of the equitable estoppel and laches claims. Putting plaintiff "through the time and expense of continued litigation on a new theory, with the possibility of additional discovery," may constitute undue prejudice. *Ascon Properties, Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1161 (9th Cir.1989) (citation omitted).

Defendants respond that plaintiffs have always been on notice of the equitable estoppel and patent misuse defenses because these defenses were pled in the original answer, and that defendants notified plaintiff of their intent to bring their new defenses as soon as the possibilities arose. Defendants further respond that all of the prior art references included in Mossinghoff's report and the proposed amended answers and counterclaims were previously included in defendants' invalidity contentions, and thus plaintiffs would have to engage in substantial analysis of the references regardless of whether defendants were allowed to cite the references in support of their inequitable conduct claims. Defendants also assert that, in any case, such a burden would not constitute prejudice for the purposes of the Federal Rules. Regarding plaintiff's discovery argument, defendants assert that, on November 15, 20 and 21, after defendants filed their motions to amend, plaintiff deposed defense witnesses who would have had knowledge regarding reliance, and therefore any prejudice in that regard has been manufactured by plaintiff by choosing not to ask the pertinent questions.

***5** The court does not find that the requirement of analyzing prior art references constitutes undue prejudice. Furthermore, any difficulties related to additional discovery can be alleviated simply by keeping fact discovery open, and by imposing upon defendants all costs related to any duplicative discovery. Plaintiff has therefore not born its burden of showing that it would be unduly prejudiced by defendants' amended answers and counterclaims.

Accordingly, defendants' motions for leave to amend will be granted, subject to certain provisions as detailed below.

II. *Motion to Strike*

Plaintiff's arguments in support of its motion to strike Mossinghoff's expert report are similar to its arguments against granting defendants leave to pursue their inequitable conduct defenses. Plaintiff argues that Mossinghoff's report should be stricken because defendants have indicated that they did not intend to pursue inequitable conduct, because the information on which Mossinghoff relies has been available to defendants throughout the litigation, and because plaintiff would be prejudiced if required to respond to Mossinghoff's report. In addition to the asserted prejudice arising from the need to analyze Mossinghoff's prior art references, plaintiff asserts that its own experts had insufficient time to respond to Mossinghoff's report within the time allotted for rebuttal reports. The court finds no greater prejudice regarding Mossinghoff's report than it does regarding defendants' proposed amended answers and counterclaims. Plaintiff's motion to strike is therefore denied.

CONCLUSION

For the foregoing reasons, the court GRANTS defendants' motions for leave to amend and DENIES plaintiff's motion to strike. Defendants' amended answers and counterclaims are deemed filed as of December 18, 2006. Defendants' equitable estoppel defenses are stricken. Fact discovery will remain open until February 12, 2006. The parties will bear their own costs regarding depositions of fact witnesses who have not yet been deposed, and regarding re-depositions of witnesses regarding laches and/or patent misuse. In

the event that plaintiff must re-depose any witnesses regarding inequitable conduct, defendants will bear the costs.

IT IS SO ORDERED.

N.D.Cal.,2006.
Semiconductor Energy Laboratory Co. Ltd. v. Chi Mei Optoelectronics Corp.
Not Reported in F.Supp.2d, 2006 WL 3826726 (N.D.Cal.)

END OF DOCUMENT